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Food Safety and Inspection Service

9 CFR Part 304, et al.

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 308, 310, 320, 327, 381, 416, and 417

[Docket No. 93–016F]

RIN 0583–AB69

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule with request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is establishing requirements applicable to meat and poultry establishments designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, reduce the incidence of foodborne illness associated with the consumption of those products and provide a new framework for modernization of the current system of meat and poultry inspection. The new regulations (1) require that each establishment develop and implement written sanitation standard operating procedures (Sanitation SOP's); (2) require regular microbial testing by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Points).

DATES: *Effective Date:* July 25, 1996, however these rules are not applicable until the dates listed below.

Applicability dates: (1) The HACCP regulations set forth in 9 CFR Part 417 and related provisions set forth in 9 CFR 304, 327, and 381 parts will be applicable as follows:

- In large establishments, defined as all establishments with 500 or more employees, on January 26, 1998.
- In smaller establishments, defined as all establishments with 10 or more employees but fewer than 500, on January 25, 1999.
- In very small establishments, defined as all establishments with fewer than 10 employees *or* annual sales of less than $2.5 million, on January 25, 2000.

(2) The Sanitation SOP's regulations set forth in 9 CFR 416 will be applicable on January 27, 1997.

(3) The *E. coli* process control testing regulations set forth in 9 CFR 310.25(a) and 381.94(a) will be applicable on January 27, 1997.

(4) The *Salmonella* pathogen reduction performance standards regulations set forth in 9 CFR 310.25(b) and 9 CFR 381.94(b) will be applicable simultaneously with applicability dates for implementation of HACCP.

Comments: Comments on specified technical aspects of the final regulations must be received on or before September 23, 1996. With respect to the HACCP final regulations, FSIS requests comments by November 22, 1996.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, DOCKET #93–016F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 4352, 1400 Independence Avenue, S.W., Washington, DC 20250–3700. All comments submitted on this rule will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 1:00 p.m., and 2:00 p.m. and 4:30 p.m., Monday through Friday. The references and baseline surveys cited in this document are available for inspection in the FSIS Docket Room.

FOR FURTHER INFORMATION CONTACT: (1) GENERAL: Dr. Judith A. Segal, Director, Policy, Evaluation, and Planning Staff, (202) 720–7773; (2) MICROBIAL TESTING: Patricia F. Stolfa, Acting Deputy Administrator, Science and Technology, (202) 205–0699.

SUPPLEMENTARY INFORMATION:

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I. Background

Overview of FSIS Food Safety Goal and Strategy

The mission of the FSIS is to ensure that meat, poultry, and egg products are safe, wholesome, and properly marked, labeled, and packaged. Regarding meat and poultry, FSIS currently carries out its food safety responsibility primarily by managing an inspection program within meat and poultry slaughter and processing establishments. This program relies heavily on FSIS inspectors to detect and correct establishment sanitation and food safety problems.

Recent outbreaks of foodborne illness and studies conducted over the past decade by the National Academy of Sciences (NAS), the U.S. General Accounting Office (GAO), and FSIS itself have established the need for fundamental change in the FSIS meat and poultry inspection program to improve food safety, reduce the risk of foodborne illness in the United States, and make better use of the Agency's resources.

FSIS has embarked on a broad effort to bring about the necessary changes in its program. In the preamble to the ''Pathogen Reduction; Hazard Analysis Critical Control Point (HACCP) Systems'' proposed rule, published in the Federal Register of February 3, 1995 (Docket #93–016P, 60 FR 6774; hereafter ''Pathogen Reduction/HACCP proposal''), FSIS traced the origins of its current program, described today's food safety challenges, and outlined a new food safety strategy for meat and poultry products. In that document, FSIS proposed new regulations to mandate adoption within meat and poultry establishments of HACCP, a science-based process control system for food safety.

The HACCP requirement and other food safety measures proposed by FSIS in the Pathogen Reduction/HACCP proposal were motivated by the critical need to fill a gap in the current regulation and inspection system and the lack of adequate measures to address the problem of pathogenic microorganisms on raw meat and poultry products.

Such bacteria, including *Salmonella, E. coli* O157:H7, *Campylobacter* and *Listeria monocytogenes,* are significant food safety hazards associated with meat and poultry products. FSIS estimates that the contamination of meat and poultry products with these bacteria results annually in as many as 4,000 deaths and 5,000,000 illnesses.

FSIS stated the goal of its food safety strategy and proposed Pathogen Reduction/HACCP regulations as follows: FSIS believes its food safety goal should be to reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur (60 FR 6785).

In establishing this goal, FSIS recognized that no single technological or procedural solution exists for the problem of foodborne illness and that the Agency's food safety goal would be achieved only through continuous efforts to improve hazard identification and prevention.

The food safety strategy FSIS outlined in the Pathogen Reduction/HACCP proposal included the following major elements: (1) provisions for systematic prevention of biological, chemical, and physical hazards through adoption by meat and poultry establishments of science-based process control systems;

(2) targeted efforts to control and reduce harmful bacteria on raw meat and poultry products; (3) adoption of food safety performance standards that provide incentives for innovation to improve food safety and to provide a measure of accountability for achieving acceptable food safety results; (4) removal of unnecessary regulatory obstacles to innovation; and (5) efforts to address hazards that arise throughout the food safety continuum from farm to table.

FSIS also stressed, as a central theme of its strategy, a need to clarify and strengthen the responsibilities of establishments for maintaining effective sanitation, following sound food safety procedures, and achieving acceptable food safety results.

FSIS Regulatory Proposals

FSIS proposed HACCP as the organizing structure for its food safety program because HACCP is the optimal framework for building science-based process control to prevent food safety hazards into food production systems. HACCP also focuses FSIS inspection on the most significant hazards and controls.

To complement HACCP, FSIS proposed to establish, for the first time, food safety performance standards for pathogenic microorganisms on raw meat and poultry products, initially as ''interim'' targets for the reduction of *Salmonella* contamination of raw carcasses and raw ground meat and poultry products. These performance standards would measure whether HACCP systems are working effectively to address food safety hazards. FSIS proposed to require that establishments conduct daily microbial testing for *Salmonella* to verify achievement of the ''targets.''

FSIS also proposed three near-term measures to speed progress on controlling and reducing pathogenic microorganisms on raw products during the proposed three year phase-in of HACCP. These proposed measures were: (1) a requirement that all establishments adopt and implement sanitation standard operating procedures (Sanitation SOP's); (2) a requirement that all slaughter establishments use at least one effective antimicrobial treatment to reduce harmful bacteria; and, (3) standards for cooling red meat carcasses to prevent the growth of harmful bacteria.

FSIS Regulatory and Inspection Reform Plans

In the Pathogen Reduction/HACCP proposal, FSIS acknowledged that it must do more than mandate HACCP and other new regulatory requirements in order to achieve its food safety goals. FSIS must also reform its existing regulations, policies, and directives to be consistent with HACCP principles and with the Agency's intention to rely more heavily on performance standards. Current FSIS regulatory requirements and procedures are generally highly detailed and prescriptive. They specify, for example, precise cooking time-and-temperature combinations for many products. Current regulations often assign to FSIS responsibility for the means used by establishments to produce safe food in a sanitary environment (e.g., FSIS requires that facility blueprints and equipment receive Agency approval before use).

As part of its regulatory reform initiative, FSIS has undertaken the conversion of current command-and-control regulations to performance standards. Command-and-control regulations, and the Inspection System Guide that FSIS inspectors use to enforce those regulations, resulted from the perceived need to achieve uniformity among federally inspected meat and poultry establishments. Technological advances introduce a new imperative, however. If establishments are to innovate, using new technologies to improve food safety, they cannot be impeded by a one-size-fits-all regulatory system. Under contemporary conditions, affording establishments the flexibility to make establishment-specific decisions outweighs the advantages of uniformly applicable rules. Recognizing this, FSIS is changing inspection to meet the needs of the new regulatory system.

Under the command-and-control-based system, the inspector assumed responsibility for ''approving'' production-associated decisions. Under the new system, industry assumes full responsibility for production decisions and execution. FSIS, having set food safety standards, monitors establishments' compliance with those standards and related requirements and under HACCP, verifies process control and pathogen reduction and control. The number of inspection tasks will be reduced, so that inspectors can focus more attention on areas of greatest risk in the meat or poultry production system within each establishment.

With the shift to HACCP and greater reliance on performance standards, establishments will be afforded greater autonomy in decision-making affecting their own operations and, in return, be expected to take responsibility for setting up site- and product appropriate process control measures to achieve FSIS-established performance standards. This approach, which is intended to increase both the incentives and the flexibility establishments need to innovate and improve food safety, requires a complete review and overhaul of the ''command-and-control'' requirements and procedures in current FSIS regulations, policies, and directives.

HACCP-based food safety strategies and performance standards also require important changes in FSIS's approach to inspection. FSIS intends to clarify the respective responsibilities of FSIS inspectors and establishment management.

In the Federal Register of December 29, 1995 (60 FR 67469), FSIS published an advance notice of proposed rulemaking (ANPR) and additional rulemaking proposals describing the Agency's strategy for the regulatory and inspectional reform required to achieve the changes required for consistency with HACCP. These changes will be accomplished before establishments are required to implement HACCP.

Change Within FSIS

Finally, achieving the Agency's food safety goals will require substantial change within FSIS itself, as the roles of establishments and Federal inspectors are realigned to accord with the HACCP philosophy. The scope of FSIS's food safety activities will also extend beyond slaughter and processing establishments to include new preventive approaches to hazards that occur during transportation, distribution, and retail, restaurant or food service sale of meat and poultry products.

This expansion of the Agency's roles will require substantial training and redeployment of employees, and will place an enormous strain on agency resources. To meet these challenges, FSIS has conducted a top-to-bottom review of its regulatory roles, resource allocation and organizational structure. Reports prepared by FSIS employees containing analysis and recommendations on these topics were described and made available for public comment in the Federal Register of September 12, 1995 (60 FR 47346). FSIS will be making the fundamental internal changes required to successfully carry out its HACCP-based farm-to-table food safety strategy. These changes within FSIS, which include a major reorganization of the Agency, will ensure that FSIS is using its resources to improve food safety consistent with its new regulatory framework.

The FSIS Pathogen Reduction/HACCP Rulemaking Process

Recognizing that HACCP and other regulatory requirements contained in the Pathogen Reduction/HACCP proposal are part of a broad overhaul of the FSIS regulatory program, and involve important changes in the responsibilities of meat and poultry establishments, FSIS has conducted a thorough and interactive rulemaking process. The Agency's goal has been to provide many opportunities for submission by the public of both written and oral comments and for interchange between FSIS and interested parties on the many major policy and technical issues involved in the reform of meat and poultry inspection.

The initial comment period was 120 days, which FSIS subsequently extended for an additional 30 days and later reopened for another 95 days. During this period, FSIS held seven informational briefings, three scientific and technical conferences, a two-day public hearing, a scoping session and six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum. Extensive oral comments were transcribed and included with written comments in the record of this rulemaking. A brief summary of the various public meetings follows.

Seven Information Briefings

Initially, FSIS held informational briefings in seven cities across the country to explain the Pathogen Reduction/HACCP proposal to the public and to answer questions. A panel of FSIS officials and scientists provided information on the proposed regulations and answered questions. These briefings were not intended to solicit comments, but to help interested parties prepare themselves to comment on the Pathogen Reduction/HACCP proposal. These briefings were held:

March 7, 1995; Oakland, California
March 14, 1995; Dallas, Texas
March 16, 1995; Chicago, Illinois
March 21, 1995; Atlanta, Georgia
March 23, 1995; New York, New York
March 30, 1995; Washington, D.C.
May 22, 1995; Kansas City, Kansas

The Kansas City session included an informational briefing and public meeting for owners and representatives of small meat and poultry establishments and other affected small businesses to discuss the Pathogen Reduction/HACCP proposal. At the meeting, many small business owners said that the Pathogen Reduction/HACCP proposal might eventually inhibit small businesses from competing with larger entities because the resulting additional costs could be borne more easily by larger companies. Three Directors of State Meat and Poultry Inspection Programs stated their views that the Pathogen Reduction/HACCP proposal might have a negative impact upon the small businesses for which they provide inspection. Consumers requested that FSIS base its decisions on the Pathogen Reduction/HACCP proposal not on industry impacts, but on what will best protect the public.

Three Scientific and Technical Conferences

FSIS held three scientific and technical conferences to foster the development of beneficial new food safety technologies, to fill gaps in scientific knowledge, and to ensure that the Agency had the best scientific information available for the rulemaking. Concerned that the typical rulemaking process would not elicit this information, the Agency invited experts on relevant subjects to the meetings, which were open to all interested parties.

The first conference, titled ''New Technology to Improve Food Safety,'' was held April 12–13, 1995, in Chicago, Illinois. This conference explored the available technology that might be introduced into the production and manufacturing of meat and poultry products to control *E. coli* O157:H7 and other harmful pathogens in the food supply. Participants included members of industry, academia, research organizations, and consumers. Additionally, Government representatives from non-food Federal regulatory agencies discussed technology development and transfer in other industries. FSIS discussed how it emphasized and encourages the approval and introduction of new technologies.

The second conference, titled ''The Role of Microbiological Testing in Verifying Food Safety,'' was held May 1–2, 1995, in Philadelphia, Pennsylvania. This meeting explored scientific issues related to the use of microbiological testing for verifying meat and poultry safety. Six persons were invited to present discussions relating to the use and limitations of microbiological testing in ensuring food safety. Twelve representatives from academia, consumer groups, industry, and exporting countries also presented talks on the concepts and methods for microbiological testing that appeared in the proposed regulation. During the comment period following the presentations, 15 people commented on the subjects covered at the meeting and in the proposed regulation.

The third conference, titled ''An Evaluation of the Role of Microbiological Criteria in Establishing Food Safety Performance Standards in Meat and Poultry Products,'' was held May 18–19, 1995, in Washington, D.C. It explored the use of microbiological criteria to establish food safety performance standards for meat and poultry products. Participants generally agreed that HACCP is an effective approach to controlling microbiological hazards in foods, and that government and industry must work together to establish microbiological criteria, sampling plans and training for food safety performance standards. Most commenters agreed that the use of an indicator organism is effective to facilitate and monitor the reduction of microbiological contamination in meat and poultry products. Diverse opinions were expressed on which indicator organisms should be chosen for each type of product.

Public Hearing

On May 30 and 31, 1995, FSIS held a public hearing in Washington, D.C., on the proposed rule.

Thirty-seven persons presented comments at the 2-day hearing. Issues and viewpoints varied greatly. For instance, requests were made to keep carcass-by-carcass inspection, but it was suggested that organoleptic inspection is outdated. While there was support for a HACCP system, many suggestions were made for changes in specific parts of the proposal, particularly microbial testing and antimicrobial treatments. Several commenters described their personal experiences with foodborne illness. Small business owners and their representatives commented on the potential financial burdens that might result from the Pathogen Reduction/HACCP proposal.

Federal-State Relations Conference

As part of the annual meeting of Directors of State Meat and Poultry Inspection Programs, FSIS held a ''Federal-State Relations Conference,'' August 21–23, 1995, in Washington, D.C. This meeting, in which the National Association of State Departments of Agriculture participated, provided an opportunity for representatives from State government to engage in an open exchange with senior USDA officials on the Pathogen Reduction/HACCP proposal. In addition to State Directors, the meeting included representatives from State Departments of Agriculture, State Health Departments and local food safety enforcement agencies; additionally, the Food and Drug Administration (FDA)

and the Association of Food and Drug Officials were participants. These parties recognized a need to better protect the public by optimizing the use of available resources. State agency representatives discussed the need for better coordination within their own States and with the Federal Government to prevent foodborne illness outbreaks. Improved food handling education for industry and consumers was seen as one of the primary ways to improve farm-to-table food safety.

Scoping Session and Six Issue-Focused Meetings

By late August, FSIS had received more than 6,800 comments on the Federal Register notice, in addition to the input obtained at the meetings and the hearing. All this information raised new issues and modified Agency thinking in some areas. In order to share new information and current thinking with its constituencies, FSIS held six issue-focused public meetings on the proposed rule and accepted written comments from those unable to attend. The meetings were announced in the Federal Register (60 FR 45380; Thursday, August 31, 1995) and held at USDA, Washington, D.C., on September 13, 14, 15, 27, 28, and 29, 1995.

FSIS framed an agenda for the meetings and provided issue papers describing current Agency thinking on the proposed rule. Before the issue-focused public meetings, FSIS held a public scoping session on August 23, 1995, to ensure that all parties had an opportunity to suggest issues for the agenda.

The issue papers provided at the six issue-focused public meetings were published in the Federal Register (60 FR 54450; Tuesday, October 24, 1995).

Food Safety Forum

A Food Safety Forum chaired by Secretary Glickman was held on November 8, 1995 to discuss food safety reform issues beyond the specific issues raised by the proposed Pathogen Reduction/HACCP proposal. The forum agenda included topics such as: (1) whether legislative changes to the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) were needed; (2) how FSIS could improve food safety by organizational change, regulatory reform, reliance on user fees, effective resource allocation and other means; (3) cooperation between USDA and State inspection programs; and (4) government and private sector roles in consumer education regarding safe food handling practices. A transcript of the forum has been included in the record for this rulemaking.

Farm-to-Table Strategy

In the preamble to its Pathogen Reduction/HACCP proposal, FSIS presented a strategy for the control of food safety hazards throughout the continuum of animal production and slaughter, and the processing, distribution, and sale of meat and poultry products. FSIS has historically focused on the manufacturing of meat and poultry products through its inspection program, but the Agency's public health mandate requires that the Agency also consider pre- and post-processing hazards as part of a comprehensive strategy to prevent foodborne illness.

This farm-to-table food safety strategy is founded on three principles:

- Hazards that could result in foodborne illness arise at each stage in the farm-to-table continuum: animal production and slaughter, and the processing, transportation, storage and retail, restaurant or food service sale of meat and poultry products. Each stage presents hazards of pathogen and other contamination and each provides opportunities for minimizing the effect of those hazards.
- Those in control of each segment of the farm-to-table continuum bear responsibility for identifying and preventing or reducing food safety hazards that are under their operational control.
- The Agency's public health mandate requires that it address foodborne illness hazards within each segment of the food production chain and implement or encourage preventative strategies that improve the whole system.

FSIS remains committed to a farm-to-table food safety strategy based on these principles. To address hazards arising within slaughter and processing establishments, FSIS proposed and is adopting in this rule significant new regulatory measures. Improving food safety before the animals reach slaughter establishments will require a different approach. The preamble to the Pathogen Reduction/HACCP proposal stated that FSIS will be cooperating with animal producers, scientists in academia, the Animal and Plant Health Inspection Service and other government agencies to develop and foster food safety measures that can be taken on the farm and through marketing channels to decrease public health hazards in animals presented for slaughter. Within this context, the voluntary application of food safety assurance programs based on HACCP principles can be useful in establishing risk reduction practices on the farm and through intermediate marketing stages to control and reduce pathogen hazards at slaughter.

FSIS expects, within the limits of available resources, to serve as a facilitator and coordinator of research and other activities designed to encourage development and implementation of animal production technologies and practices that can improve food safety. FSIS also intends to offer its expertise to assist State health and agricultural officials, when requested, during outbreak investigations of foodborne illnesses to learn more about potential risk factors. FSIS does not intend nor is FSIS authorized, to mandate production practices on the farm, but does expect that continued public concern about foodborne pathogens and adoption of HACCP and food safety performance standards within slaughter and processing establishments will increase incentives for improving food safety practices at the animal production level.

The post-processing transportation, storage, and retail, restaurant or food service sectors are also important links in the chain of responsibility for food safety. In these areas, FDA and State and local governments share authority and responsibility for oversight of meat and poultry products outside of official establishments. FSIS and FDA are collaborating in the development of standards governing the safety of potentially hazardous foods, including meat and poultry, eggs, and seafood, during transportation and storage, with particular emphasis on proper cooling to minimize the growth of pathogenic microorganisms, and on disclosure of prior cargoes in transport vehicles. This effort will be discussed in a forthcoming advance notice of proposed rulemaking.

In the retail, restaurant and food service areas, FSIS and FDA are working in concert with State and local food regulatory officials to foster adoption of updated, uniform, science-based standards, including mandates for HACCP process controls for high-risk processing and packaging operations. State and local authorities have assumed primary responsibility for food safety oversight of retail, restaurant and food service operations, but FSIS and FDA, working through the Conference on Food Protection and other collaborative mechanisms, provide expertise and leadership to support local authorities and foster development of sound food safety standards and practices nationwide. FSIS is cooperating with FDA to update the Food Code, a set of model ordinances recommended for adoption by the

States, to ensure meat and poultry safety is adequately addressed in retail, restaurant and food service settings.

Even as progress is made in reducing contamination of food by harmful bacteria and other safety hazards at the production, processing and subsequent commercial stages of the farm-to-table continuum, it will remain critically important that individual consumers follow safe food handling practices. Proper storage, preparation, and cooking of meat and poultry products are essential to achieving the goal of reducing the risk of foodborne illness to the maximum extent possible. FSIS intends to augment its food handler and consumer education efforts by expanding its collaboration with the meat and poultry industry, other government agencies, consumer and public interest groups, educators, and the media to effectively develop and deliver food safety education and information to the public.

The HACCP requirements and other regulations FSIS is adopting in this final rule will ensure that inspected establishments are taking appropriate measures to reduce hazards at critical stages where the risk of initial contamination is greatest. The public health benefits of these measures, however, are only a part of a comprehensive food safety strategy that seeks to minimize hazards throughout the farm-to-table continuum.

General Overview of the Comments and the Final Rule

HACCP and Performance Standards

The FSIS proposal to require adoption of HACCP in meat and poultry establishments was widely endorsed by comments from large and small businesses, the scientific and public health communities, consumers, and public interest organizations. Commenters strongly supported the concept that meat and poultry establishments should systematically build science-based food safety measures into their production processes following the seven HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Food (NACMCF). Although many commenters requested clarification of how FSIS intends to implement HACCP and conduct inspection under HACCP, the principal critical comments concerned costs and the practicality of using HACCP in very small establishments. FSIS is adopting the HACCP requirements, based on the NACMCF principles, essentially as proposed.

From a food safety standpoint, the most important objective of this rulemaking is to build into food production processes, and into the system of FSIS regulation and oversight, effective measures to reduce and control harmful bacteria on raw meat and poultry products. This will not by itself solve the problem of foodborne illness associated with meat and poultry products. Effective measures are needed throughout the farm-to-table continuum, but this rulemaking will fill the most critical gap in the current system of meat and poultry inspection. While products sold in cooked or otherwise ready-to-eat forms are currently subject to controls and regulatory standards designed to eliminate harmful bacteria, products sold raw are not currently subject, as a general matter, to any such controls or standards.

FSIS has concluded that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for controlling and reducing harmful bacteria on raw meat and poultry products. HACCP provides the framework for industry to set up science-based process controls that establishments can validate as effective for controlling and reducing harmful bacteria. Performance standards tell establishments what degree of effectiveness their HACCP plans will be expected to achieve and provide a necessary tool of accountability for achieving acceptable food safety performance. Science-based process control, as embodied in HACCP, and appropriate performance standards are inextricably intertwined in the Agency's regulatory strategy for improving food safety. Neither is sufficient by itself, but, when combined, they are the basis upon which FSIS expects significant reductions in the incidence and levels of harmful bacteria on raw meat and poultry products and, in turn, significant reductions in foodborne illness.

The proposed interim targets for pathogen reduction based on *Salmonella* generated widely diverse comments. Commenters supported the goal of pathogen reduction, and many recognized some role for microbial testing and the need for a microbial reduction target or performance standard. Some commenters argued that the proposed testing regimen (a single sample per species per day) was inadequate for its purpose in large establishments, while others argued it was too burdensome in small establishments. Some commenters specifically supported the proposed *Salmonella* reduction targets and the daily testing requirements. Many, however, criticized the proposed testing requirements and considered *Salmonella* testing less useful than generic *E. coli* testing as an indicator of whether process controls in slaughter establishments are effectively preventing fecal contamination, the primary pathway for pathogen contamination. At the scientific conference on the role of microbial testing held in Philadelphia, broad support also was expressed for using generic *E. coli* rather than *Salmonella* as a process control indicator.

Based on public comments, FSIS has modified its approach to establishing microbial performance standards. FSIS believes that testing for generic *E. coli* is the appropriate and necessary means by which meat and poultry slaughter establishments must verify their process controls. FSIS reviewed written comments received on the original proposal and comments made at the scientific conferences and public meetings, as well as available scientific data, and has decided to require slaughter establishments to conduct testing for generic *E. coli* to verify process controls. Establishments will be required to test for *E. coli* at a frequency that takes into account their volume of production. FSIS is seeking additional scientific and economic data that may help to further improve the *E. coli* testing protocols.

FSIS is also establishing performance criteria based on national microbiological baseline surveys. The criteria are not regulatory standards but rather provide a benchmark for use by slaughter establishments in evaluating *E. coli* test results. Test results that do not meet the performance criteria will be an indication that the slaughter establishment may not be maintaining adequate process control for fecal contamination and associated bacteria. Such results will be used in conjunction with other information to evaluate and make appropriate adjustments to ensure adequate process control for fecal contamination and associated bacteria.

FSIS is also establishing pathogen reduction performance standards for *Salmonella* that will require all slaughter establishments to reduce the incidence of *Salmonella* contamination of finished meat and poultry carcasses below the national baseline prevalence as established by the most recent FSIS national microbiological baseline data for each major species. FSIS will conduct *Salmonella* testing in slaughter establishments to detect whether they are meeting the pathogen reduction performance standards, and will require corrective action or take regulatory

action, as appropriate, to ensure establishments are meeting the pathogen reduction standards.

Pathogen-specific performance standards for raw products are an essential component of the FSIS food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products. The *Salmonella* standards being established in this final rule, which are based on the current national baseline prevalence of *Salmonella* (expressed as a percentage of contaminated carcasses), are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards. FSIS plans to repeat its baseline surveys and collect substantial additional data through other means and, on that basis, adjust the *Salmonella* performance standards and possibly set standards for additional pathogens, as appropriate. Also, FSIS will continue to explore establishing pathogen-specific performance standards based on the levels of contamination (i.e., the number of organisms) on a carcass. Future FSIS efforts on such performance standards will reflect the fact that achieving the food safety goal of reducing foodborne illness to the maximum extent possible will require continuous efforts and improvement over a substantial period.

Sanitation SOP's, Antimicrobial Treatments, and Cooling Requirements for Raw Meat and Poultry Products

Comments generally supported the objectives of the three near-term measures for raw meat and poultry products proposed by FSIS, Sanitation SOP's, antimicrobial treatments, and carcass cooling standards, and most commenters agreed that Sanitation SOP's should be a required element of any meat and poultry establishment's food safety program. Many commenters objected, however, to FSIS mandated antimicrobial treatments in slaughter establishments and carcass cooling standards for red meat prior to the implementation of HACCP. Although most comments generally agreed that antimicrobial treatments would play an important role in many slaughter establishments' HACCP plans, and that proper carcass cooling would be an essential part of any HACCP plan for raw meat and poultry products, these commenters argued that mandating a particular approach to antimicrobial treatments or carcass cooling would be inconsistent with the HACCP concept that establishment management is responsible for designing a system of controls appropriate for each establishment. They also argued that mandating antimicrobial treatments was unnecessary if establishments were required to meet pathogen reduction performance standards. Similarly, with respect to the proposed requirement that establishments cool red meat carcasses following specific cooling rate standards prescribed by FSIS, commenters argued that HACCP, reinforced by performance standards, would ensure proper carcass cooling. Many commenters said that the specific time-and-temperature requirements proposed by FSIS were often not feasible, posed worker safety concerns, and would divert effort and resources that could be used more productively in preparing for implementation of HACCP.

Based on the comments, FSIS has reconsidered its approach to the proposed near-term measures. FSIS believes that its regulatory program and the food safety efforts of the meat and poultry industry should be focused on making a transition to HACCP as rapidly and effectively as possible and that FSIS should not mandate any near-term measures that would not be expected to continue as mandatory elements of a HACCP-based system.

FSIS has decided to adopt final rules that mandate Sanitation SOP's. Good sanitation is a critical foundation for HACCP, and Sanitation SOP's are an essential element of the FSIS effort to more clearly define establishment and inspector responsibilities, and better focus both the establishment management and FSIS on those elements of daily sanitation that relate most directly to the risk of product contamination. Near-term implementation of Sanitation SOP's will facilitate the transition to HACCP.

FSIS has decided not to mandate antimicrobial treatments in slaughter establishments. The Agency expects that antimicrobial treatments will play an important role in the design of slaughter HACCP plans as establishments institute controls that are effective in reducing pathogens and meeting FSIS performance standards. As a general matter, however, FSIS does not intend to mandate the specific controls that establishments must adopt in their HACCP plans. In the case of antimicrobial treatments, FSIS believes that improvement in food safety would be better served by providing establishments the incentive and flexibility to incorporate antimicrobial treatments in any manner they judge most effective for their operations to meet FSIS-established performance standards for reducing bacterial contamination.

With respect to carcass cooling, FSIS continues to believe that, in a HACCP environment, appropriate performance standards are needed for the cooling of carcasses and raw meat and poultry products to prevent the growth of harmful bacteria. After consideration of the comments, FSIS has concluded, however, that the specific time-and-temperature combinations proposed by FSIS were too restrictive and that a scientifically sound and effective strategy for preventing the growth of pathogens through proper cooling must apply not only within, but also beyond, FSIS-inspected establishments. Thus, instead of including requirements for carcass cooling in this final rule, FSIS intends to extend this rulemaking to consider alternative approaches to performance standards for cooling within establishments. Concurrently, FSIS also intends to develop rulemaking covering the adoption of standards for cooling of raw products during transportation, storage, and retail, restaurant or food service sale. FSIS anticipates adopting performance standards designed to minimize the growth of harmful bacteria on raw products that establishments will be required to meet through their HACCP plans. FSIS will announce in a future issue of the Federal Register a three-day public conference to gather further scientific information and public comment on these subjects.

Timetable for Implementation

Federally Inspected Establishments

FSIS proposed an implementation timetable that would have phased in the near-term measures and HACCP over a period of time beginning 90 days and ending three years after publication of the final rule. Sanitation SOP's and the other near-term measures, as well as the proposed microbial sampling by establishments for *Salmonella*, were to begin 90 days after publication. Slaughter establishments were to be held accountable for meeting the *Salmonella* targets two years after publication.

FSIS proposed to phase in HACCP over a one to three-year period, primarily on a process-by-process basis. For example, raw ground products would be subject to the HACCP requirements one year after publication of the final rule, while all slaughter establishments would be required to start HACCP thirty months (2½ years) after publication of the final rule. However, FSIS proposed that establishments with annual sales of less than $2.5 million be given three years to

comply with the HACCP requirement, regardless of the processes they run.

Some commenters said the proposed implementation timetable was too slow, considering the seriousness of the food safety issues involved and the familiarity with HACCP that already exists among many in the industry. Other commenters pointed out that many larger establishments have already adopted HACCP. Some said the Pathogen Reduction/HACCP proposal placed excessive burdens on smaller establishments, which were said to be less prepared technically and financially to carry out HACCP. Wide support was voiced for implementing HACCP as promptly as practicable, taking into account the diversity of businesses involved and the different levels of readiness for HACCP.

FSIS has considered these comments and has also re-evaluated the proposed timetable for implementation of all requirements discussed above in light of preparations FSIS will itself have to make to implement HACCP, including the training of inspection and other agency employees. FSIS believes it is important to bring the meat and poultry supply under HACCP-based process control and to implement other elements of its food safety strategy as rapidly as possible. It is also important to have a timetable that is realistic for implementing this fundamental transformation in how FSIS regulates meat and poultry establishments. FSIS is modifying the timetable for implementation in a way that achieves both goals.

The Sanitation SOP's requirements will take effect 6 months after publication of these final rules, rather than 90 days as originally proposed.

Establishments slaughtering livestock or poultry will be required to begin process control verification testing for generic *E. coli* 6 months after publication of this final rule.

FSIS will begin holding slaughter establishments and establishments producing raw ground products accountable for achieving *Salmonella* pathogen reduction performance standards at the time they will be required to implement HACCP under the phase-in schedule described below, rather than the single, two-year delayed effective date originally proposed. Beginning approximately three months after publication of this final rule, FSIS will initiate its pre-enforcement *Salmonella* testing program. This establishment-by-establishment *Salmonella* prevalence survey will provide critical data on the performance of establishments; it will inform establishments of their performance, and guide FSIS enforcement testing and compliance strategies after establishments are required to meet the *Salmonella* performance standards.

In response to comments, FSIS is modifying the proposed timetable for implementing HACCP from one based primarily on production process in an establishment to one based on establishment size. Under this approach, the pace at which most of the Nation's meat and poultry supply comes under HACCP-based process control will be accelerated. Most important, slaughter establishments that account for 75% of the annual meat and poultry production in the United States will be required to implement HACCP 18 months after publication of these final rules, rather than 30 months after publication as originally proposed. At the same time, very small establishments (those with fewer than 10 employees *or* with annual sales of less than $2.5 million, together accounting for less than 2% of meat and poultry production) will be provided an additional six months beyond the proposed three years to implement HACCP.

Under this timetable, FSIS gains needed time to develop and sequence inspector training and other preparatory activities. Also, establishments that carry out multiple processes (such as the so-called ''combo'' establishments that both slaughter animals and grind raw products) will be able to implement HACCP on a more coherent establishment-wide basis, rather than on a process-by-process basis. A detailed description of the implementation timetable and its rationale is provided in section II of this preamble.

State-Inspected Establishments

Both the FMIA and PPIA direct Federal cooperation with States in developing and administering intrastate inspection programs that include mandatory antemortem and postmortem inspection, reinspection, and sanitation requirements which are ''at least equal to'' Federal requirements. Consequently, each State receiving matching Federal funds for the administration of its intrastate meat and poultry inspection program must implement Pathogen Reduction/HACCP programs that are at least equal to provisions set forth in this final rule. FSIS will coordinate closely with States that maintain federally supported meat and poultry inspection programs to ensure that Pathogen Reduction/HACCP is implemented in all intrastate establishments.

Foreign-Inspected Establishments

In order to export meat or poultry to the United States, foreign countries must establish a system of inspection that is equivalent to the system in this country. Determinations of equivalency made by U.S. reviewers of foreign meat and poultry inspection systems are currently based upon (1) the presence or lack of specific regulatory requirements and (2) how those requirements are enforced. As Pathogen Reduction/HACCP regulatory provisions are implemented in the U.S. domestic market, foreign countries will concurrently be evaluated to ascertain whether their inspection systems provide equivalent regulatory provisions with adequate levels of enforcement.

Implementation Conferences

FSIS plans to convene a three-day HACCP implementation conference in Washington, DC, about 60 days after publication of this final rule. Similar sessions will follow in various cities around the country.

The purpose of the implementation conferences is to continue, and build upon, the dialogue among interested parties that occurred during the six days of public meetings FSIS conducted in September 1995 on the proposed rule. FSIS anticipates that the following topics will be discussed at the implementation conferences: (1) status of FSIS efforts to develop generic model HACCP plans and conduct small establishment HACCP demonstration projects; (2) the draft guidance materials published as Appendices; (3) the revised HACCP implementation schedule and certain technical aspects of the regulations being promulgated in this final rule; (4) other implementation issues identified by the public; (5) methods to achieve the goal of consistent training for FSIS and industry employees; and (6) due process and enforcement issues.

In addition, FSIS plans to conduct two public conferences on technical issues related to *E. coli* testing. The first conference is planned to be held approximately 45 days into the 60-day comment period following publication of this rule. The public conference will be led by a panel of scientists from FSIS and other government agencies who will listen to testimony and review comments received on these technical issues and share their observations and opinions. FSIS will consider their input as well as all comments received as the basis for any necessary technical amendments which will be completed at least 30 days before the

implementation date. The second conference is tentatively planned for approximately 9 months following publication of this rule. This conference would be an opportunity for the industry and others to discuss with FSIS new information based on about 3 months of testing experience that may bear on these same issues and might allow for further adjustments of protocols before FSIS inspectors are tasked, about three months later, with comparing test results to the national criteria as part of their inspection routine. FSIS will publish further, more detailed notice of these conferences in future issues of the Federal Register.

Request for Comments

These final rules have benefitted from substantial public comment and the dialogue that took place during extensive public meetings with interested groups and individuals. Following the close of the comment period on November 13, 1995, several industry associations requested that these regulations be issued as ''interim'' final rules with a 30-day opportunity for further public comment prior to the rules becoming final. FSIS is denying this request because the HACCP principles and other major elements of these final regulations have already been the subject of unusually extensive public comment and dialogue, and it is important to proceed toward implementation of these new food safety measures as promptly as possible.

FSIS seeks comments, however, on certain technical aspects of these final regulations and on the guidelines (published here as Appendices) that will play a role in implementation of sanitation SOP's, microbial testing, and HACCP. FSIS requests comments no later than September 23, 1996 on (1) technical issues that are associated with *E. coli* testing; (2) the *E. coli* performance criteria, and (3) the Sanitation SOP's Guideline and Model Sanitation SOP's, published at Appendices A and B, respectively.

Based on comments it receives, FSIS will make any necessary revisions in the draft guidelines and technical aspects of the *E. coli* testing regulation prior to the effective date of the affected regulatory requirements.

With respect to the HACCP final regulations, FSIS requests comments by November 22, 1996 on (1) the revised HACCP implementation timetable, including any factual information that commenters believe would justify any adjustments in the announced effective dates; (2) the Hazards and Preventive Measures Guide (published at Appendix D) and (3) the Guidebook for the Preparation of HACCP Plans (published at Appendix C).

II. Hazard Analysis and Critical Control Point Systems

Overview of Final Rule

This final rule requires that federally inspected establishments implement HACCP systems to address hazards that are reasonably likely to occur in their operations. The HACCP systems mandated by this final rule focus on attributes affecting product safety, not those affecting economic adulteration or quality. On the effective dates of this final rule, FSIS will begin verifying HACCP system operations as part of its inspection program. Establishments will be required to maintain a HACCP plan covering every meat or poultry product produced for human food. Processes for which HACCP plans must be developed include slaughter for all species; raw ground meat or poultry products; raw product, not ground (e.g., meat cuts or whole or cut-up birds); shelf-stable nonheat-treated products (e.g., jerky); shelf-stable heat-treated products (e.g., edible fats); thermally processed/commercially sterile products (e.g., canned soup); fully cooked nonshelf-stable products (e.g., canned hams that must be refrigerated); not fully cooked/heat-treated products (e.g., char-marked beef patties); and nonshelf-stable products with secondary inhibitors (e.g., fermented sausage). It should be noted that the category of raw, not ground product can include products with certain additional processing steps beyond carcass dressing, such as cutting up whole carcasses or marinating meat or poultry products.

History and Background of HACCP

HACCP is a conceptually simple system whereby meat and poultry establishments can identify and evaluate the food safety hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits, monitor the performance of controls, and maintain records routinely. HACCP is the best system currently available for maximizing the safety of the nation's food supply.

HACCP systems have been recommended for use in the food industry for more than a quarter century. The HACCP concept has been promoted by government and scientific groups and incorporated for many years in FSIS's and FDA's regulations on canned foods. Committees of the NAS have recommended that government agencies with responsibility for controlling microbiological hazards in foods, including FSIS, promulgate regulations requiring industry to utilize the HACCP system for food protection purposes.

The NACMCF, which was established in accordance with a NAS committee recommendation, endorsed the HACCP system as an effective and rational approach to the assurance of food safety. In its March 20, 1992, publication ''Hazard Analysis and Critical Control Point System,'' NACMCF advocated the standardization of the HACCP principles and their application by industry and regulatory authorities, with each food-producing establishment developing a HACCP system tailored to its individual product, processing, and distribution conditions.

The U.S. General Accounting Office, in a series of reports between 1992 and 1994, endorsed HACCP as an effective, scientific, risk-based system for protecting the public from foodborne illness. On December 18, 1995, the FDA published final rules requiring the adoption of HACCP systems in seafood processing plants (60 FR 65096).

International and foreign government bodies have also advocated the adoption of HACCP systems. The International Commission on Microbiological Specifications for Foods (ICMSF), in its 1988 report, ''HACCP in Microbiological Safety and Quality,'' endorsed the use of HACCP systems in food production, processing, and handling. In 1993, the Food and Agriculture Organization/World Health Organization Codex Alimentarius Commission adopted a HACCP document that now serves as a guide for countries to incorporate HACCP principles into their food industries. The seven HACCP principles adopted by the Codex Alimentarius Commission are identical to those adopted by the NACMCF and on which this final rule is based. HACCP principles have been embodied in recent European Union regulatory directives and in food protection programs conducted by the governments of Canada, New Zealand, and Australia.

The Seven HACCP Principles

The seven HACCP principles recommended by NACMCF in 1992 provide the framework for this final rule. While the seven principles are not explicitly listed as such in the codified regulatory text, they are embodied in the regulatory requirements for a hazard analysis in § 417.2(a); the elements of a HACCP plan in § 417.2 (b) and (c); the corrective action requirements in § 417.3; the validation, verification, and reassessment requirements in § 417.4; and the record review and maintenance

requirements in § 417.5. The seven HACCP principles are discussed below.

Principle No. 1: A hazard analysis of each process must be carried out. The purpose of the analysis is to identify and list the food safety hazards reasonably likely to occur in the production process for a particular product and the preventive measures necessary to control the hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be adulterated or otherwise unsafe for human consumption. A listed hazard must be of such a nature that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food.

Examples of questions to be considered in a hazard analysis include: (1) What potential hazards may be present in the animals to be slaughtered or the raw materials to be processed? (2) What are the avenues that might lead to contamination of finished product with pathogenic microorganisms, hazardous chemicals, or other potentially hazardous contaminants? (3) What is the likelihood of such contamination and what are the means for preventing it? (4) Does the food contain any ingredient historically associated with a known microbiological hazard? (5) Does the food permit survival or multiplication of pathogens or toxin formation during processing? (6) Does the process include a controllable processing step that destroys pathogens? (7) Is it likely that the food will contain pathogens and are they likely to increase during the times and conditions under which the food is normally stored before being consumed? (8) What product safety devices are used to enhance consumer safety (e.g., metal detectors, filters, thermocouples)? (9) Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins? (10) Is the product epidemiologically linked to a foodborne disease?

Principle No. 2: The critical control points (CCP) of each process must be identified. A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. All hazards identified during the hazard analysis must be addressed. The information developed during the hazard analysis should enable the establishment to identify which steps in their processes are CCP's.

Identification of CCP's for controlling microbial hazards throughout the production process is particularly important because these hazards are the primary cause of foodborne illness. The establishment may find the CCP decision tree developed by the NACMCF useful in the CCP identification process (see Figure 1). However, the use of this technique in identifying CCP's is not required by this final rule.

Principle No. 3: The critical limits for preventive measures associated with each identified CCP must be established.

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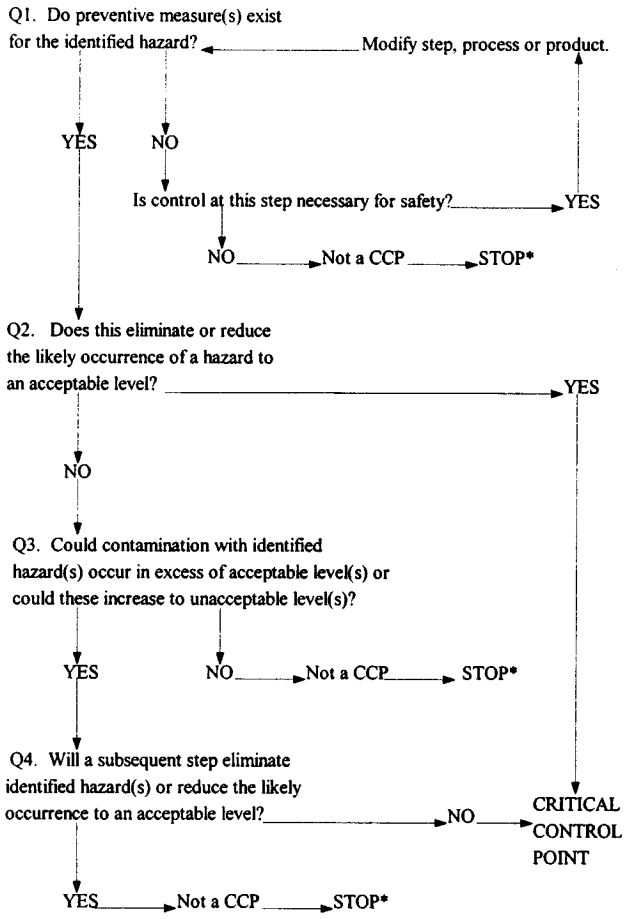
Figure 1. CCP Decision Tree (Apply at each step of process with an identified hazard.)



*Proceed to next step in the described process.

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A critical limit is the maximum or minimum value to which a process parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the identified physical, biological, or chemical food safety hazard. Critical limits are most often based on process parameters such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or survival of target pathogens. Critical limits should be based on applicable FSIS regulations or guidelines, FDA tolerances and action levels, scientific and technical literature, surveys, experimental studies, or the recommendations of recognized experts in the industry, academia, or trade associations.

Establishments are encouraged to establish critical limits more stringent than those now required by FSIS regulations or suggested by scientific data to ensure that regulatory requirements are routinely met, even when minor deviations occur.

Principle No. 4: The monitoring requirements for CCP's must be established. Monitoring is an integral part of HACCP and consists of observations or measurements taken to assess whether a CCP is within the established critical limit. Continuous monitoring is preferred, but when it is not feasible, monitoring frequencies must be sufficient to ensure that the CCP is under control.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Personnel assigned the monitoring activities should be properly trained to accurately record all results, including any deviations, so that immediate corrective actions may be taken.

Principle No. 5: The HACCP plan must include corrective action to be taken when monitoring indicates that there is a deviation from a critical limit at a critical control point. Although the process of developing a HACCP plan emphasizes organized and preventive thinking about what is occurring as the meat or poultry product is being manufactured, the existence of a HACCP plan does not guarantee that problems will not arise. For this reason, the identification of a planned set of activities to address deviations is an important part of a HACCP plan. In such instances, corrective action plans must be in place to determine the disposition of the potentially unsafe or noncompliant product and to identify and correct the cause of the deviation. The HACCP plan itself might require modification, perhaps in the form of a new critical limit, or of an additional CCP.

Principle No. 6: Effective recordkeeping procedures that document the entire HACCP system must be developed and maintained. A HACCP system will not work unless consistent, reliable records are generated during the operation of the plan, and those records are maintained and available for review. One of the principal benefits of a HACCP process control system to both industry and regulatory officials is the availability of objective, relevant data.

Principle No. 7: HACCP systems must be systematically verified. After initial validation that the HACCP system can work correctly and effectively with respect to the hazards, the system must be verified periodically. Periodic verification involves the use of methods, procedures, or tests in addition to those used for monitoring, to determine whether the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation to achieve its food safety objective.

In the NACMCF explanation of the verification principle, which FSIS is following, four processes are involved in the verification of the establishment's HACCP system. The establishment is responsible for the first three; FSIS is responsible for the fourth. The first is the scientific and technical process, known as ''validation,'' for determining that the CCP's and associated critical limits are adequate and sufficient to control likely hazards. The second process is to ensure, initially and on an ongoing basis, that the entire HACCP system functions properly. The third consists of documented, periodic, reassessment of the HACCP plan. The fourth process defines FSIS's responsibility for certain actions (Government verification) to ensure that the establishment's HACCP system is functioning adequately.

HACCP and the FSIS Food Safety Strategy

The food safety goal of FSIS's Pathogen Reduction/HACCP rulemaking proposal is to reduce the risk of foodborne illness from meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible preventive and corrective measures are taken at each stage of the food production process where food safety hazards occur. There is no single technological or regulatory solution to the problem of foodborne illness. Continuous efforts are required by industry and government to improve methods for identifying and preventing hazards and to minimize the risk of illness.

FSIS proposed HACCP as the framework for carrying out its comprehensive strategy to improve food safety. HACCP, combined with the other measures required by this rulemaking, will substantially improve the ability of meat and poultry establishments and FSIS to target and systematically prevent and reduce food safety hazards and, working together, to continuously improve food safety as science and technology improve. These measures fill a critical gap in the current system with respect to the control and reduction of harmful bacteria on raw meat and poultry products and will, over time, significantly reduce the risk of foodborne illness.

FSIS's meat and poultry inspection program currently addresses and will continue to address many matters of importance to the safety and quality of the food supply, including supervision of industry compliance with sanitation standards, exclusion of diseased animals from the food supply, examination of carcasses for other visible defects that can affect safety and quality, and inspecting for economic adulteration. These activities respond to some of the public's most basic expectations regarding the safety and quality of the food supply and reflect the standards and requirements established by Congress in the laws FSIS administers. FSIS is strongly committed to the most effective and efficient implementation of these statutory requirements.

This final rule initiates a fundamental change in the inspection program to better meet FSIS's paramount obligation to protect the public health. Specifically, it addresses in a substantive way the public health problem of foodborne illness associated with the consumption of meat and poultry products. It does so in large part by better delineating and clarifying the respective roles of industry and FSIS to ensure that meat and poultry products are produced in accordance with sanitation and safety standards and are not adulterated or misbranded within the meaning of the FMIA and PPIA. This rule makes clear that the industry is responsible for producing and marketing products that are safe, unadulterated, and properly labeled and packaged. FSIS is responsible for inspecting products and facilities to verify that the statutory requirements are being met and for taking appropriate compliance and enforcement actions when the requirements are not being met.

The line between the responsibilities of FSIS and those of the industry has often been blurred. This is because of the prescriptive nature of the current FSIS inspection program and the tendency for some establishments to rely on FSIS inspectors to do what is necessary to direct the correction of deficiencies and to ensure that outgoing products are safe, and not adulterated or misbranded. Some establishments operate on the assumption that if the inspector identifies no problem, their meat or poultry products may be entered into commerce. This is even more problematic because the current inspection system is based primarily on organoleptic methods that cannot detect the hazards of pathogenic microorganisms. The line has also been blurred because of the excessive reliance of the FSIS inspection program on the detection and correction of problems after the fact, rather than assurance that problems will be prevented, systematically by design, in the first place.

The changes FSIS will effect with this final rule will eliminate this confusion and delineate clearly the respective responsibilities of FSIS and industry. The changes constitute a fundamental shift in the FSIS regulatory program, which FSIS is convinced will significantly enhance the effectiveness of the program and substantially reduce the risk of foodborne illness.

Preparing for HACCP Implementation

For the new FSIS food safety strategy, particularly HACCP, to be successful, FSIS must reconsider its current reliance on prescriptive command-and-control regulations and instead rely more on performance standards. Not only do command-and-control regulations prescribe the means by which establishments are to achieve a particular food safety objective, but they are susceptible of being enforced in a manner that leads to the inspector's substantial involvement in management decisionmaking. Performance standards, on the other hand, prescribe the objectives or levels of performance (such as pathogen reduction standards for raw product) establishments must achieve, but afford establishments flexibility in determining how to achieve those performance objectives. The shift to performance standards and the concomitant increase in flexibility for meat and poultry establishments reflect FSIS's commitment to stimulating the innovative capacity of the meat and poultry and allied industries to improve the safety of their products.

Command-and-control regulations are generally incompatible with HACCP and the FSIS food safety strategy, and conflict with the goal of reducing the

risk of foodborne illness on a continuing basis. They deprive establishments of the flexibility to innovate, one of the primary advantages of HACCP, and undercut the clear delineation of food safety responsibilities between industry and FSIS, on which the FSIS strategy is based. Therefore, to prepare for HACCP implementation, FSIS is conducting a thorough review of its current regulations and will, to the maximum extent possible, convert its command-and-control regulations to performance standards. (For a discussion of this regulatory reform initiative, see advance notice of proposed rulemaking published on December 29, 1995; Docket No. 95–008A; 60 FR 67469).

Inspection Under HACCP

HACCP-oriented food safety inspection changes FSIS's approach to overseeing the safety of meat and poultry products. Under this new approach, FSIS will rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety. FSIS will restructure its inspection tasks and rely on review techniques aimed at systems designed for preventing problems that could lead to the production of unsafe meat or poultry products. FSIS will carry out various activities to ensure that industry HACCP systems meet the requirements of this rule, and are functioning as designed.

Beginning on the effective date of the regulation for a particular establishment, FSIS personnel will carry out a general review of an establishment's HACCP plan to determine its conformance with the seven HACCP principles. This evaluation will take place at the time of start-up or initial implementation of the HACCP plan for new establishments. Subsequently, special teams of FSIS personnel will work in conjunction with assigned inspectors to conduct in-depth reviews, on a regular basis, of the establishment's current HACCP plan to verify their scientific validity and ongoing adequacy for preventing food safety hazards. Further, at any time that the HACCP plan is revised or amended, FSIS personnel assigned to the establishment will review the plan to determine if it is in conformance with regulatory requirements.

FSIS will also carry out its verification activities by focusing on an establishment's ongoing compliance with HACCP-related requirements. Inspectors will be assigned to carry out the verification activities under HACCP-oriented inspection in much the same way as they receive their assignment schedules under the current system. A verification activity might include reviewing all establishment monitoring records for a process, reviewing establishment records for a production lot, direct observation of CCP controls as conducted by establishment employees, collecting samples for FSIS laboratory analysis, or verifying establishment verification activities for a process.

As HACCP-based process control is established in meat and poultry establishments, with its continuous monitoring by the establishment and oversight by FSIS, opportunities to incorporate new technologies and continuously improve food safety will be more readily identified. The continuous monitoring and verification of production processes and controls by the establishment and FSIS, which is an essential feature of the HACCP system, will set the stage for further food safety improvements.

Many commenters on the proposal expressed concern that the number of inspectors would decline and the quality of Federal inspection would diminish with HACCP implementation. FSIS expects HACCP to enhance the effectiveness of its meat and poultry inspection, not diminish it. Implementation of this final rule will clarify that the meat and poultry industries and FSIS have separate responsibilities for safety of the food supply. Industry will be required to establish process control systems for all forms of meat and poultry slaughter and processing and meet appropriate regulatory performance standards. By vigorous inspectional oversight of HACCP and reliance on objective test results and other observations to verify compliance with performance standards, FSIS inspectors will be better able to ensure that products leaving FSIS establishments are safe. Also, FSIS will be better able to allocate its resources to areas of greatest risk. HACCP implementation will move both industry and FSIS toward a more preventive approach to ensuring the safety of meat and poultry.

A cross-section of consumer groups, FSIS employees, and meat and poultry establishments stated that each livestock and bird carcass must continue to be examined by trained, experienced FSIS inspectors and veterinarians, even under a HACCP system. They stated that carcass-by-carcass inspection is essential to identifying animals with diseases that are transmissible to humans and other disease conditions causing animals to be unacceptable for human food. About 2,000 commenters maintained that HACCP is not, nor should it be, a substitute for carcass-by-carcass inspection by Federal inspectors.

Carcass-by-carcass inspection is a legal requirement that binds both FSIS and the industry. It also addresses nonsafety considerations that are not addressed by HACCP. Therefore, HACCP cannot substitute for carcass-by-carcass examination. However, in light of HACCP, which will improve process control in slaughter establishments, FSIS plans to examine current tasks related to carcass-by-carcass inspection and determine what changes, if any, could improve the effectiveness of inspection or result in a more productive use of resources.

Many commenters representing the meat and poultry industries argued that proposed pathogen reduction and HACCP system requirements layer an additional set of regulations and an additional program of inspection onto the current meat and poultry inspection system. These commenters recommended that FSIS review and revise or eliminate current regulations, directives and other FSIS guidance prior to finalizing the proposal as a means for ensuring they are compatible with pathogen reduction and HACCP requirements. Commenters stated that this review would not only mitigate inspection burdens imposed on industry by the proposal, but would facilitate the smooth implementation of pathogen reduction and HACCP requirements, as well.

FSIS agrees that regulations, directives, and guidelines should be consistent with HACCP and is currently reviewing regulations, directives, and other guidance materials governing meat and poultry inspection. Those regulations, directives, and guidance documents that are inconsistent or incompatible with HACCP principles and procedures will be amended or revoked. This task will not only ensure consistency throughout the regulations, directives, and other documents, but will reduce duplication and help focus inspection on the most serious risks to food safety.

Implementation Schedule

FSIS proposed to phase in implementation of HACCP during a 12 to 36-month period primarily on a process-by-process basis, except that all ''small'' establishments (defined as establishments with annual sales of less than $2.5 million) would be allowed the full 36 months to implement their HACCP plans.

FSIS received numerous comments on the proposed implementation schedule. Many commenters from meat and

poultry establishments said the proposed period for implementing HACCP was too short. These commenters requested more time to develop HACCP plans, train employees, and purchase or upgrade equipment. Many commenters requested that small businesses be granted more time to implement HACCP so they could amortize the costs of hazard analysis and plan development, equipment purchases, personnel training and records maintenance. A number of commenters suggested alternative timetables for implementation, ranging from three to fifteen years.

Several consumer groups argued that the proposed implementation schedule was too slow and would compromise public health because serious outbreaks of foodborne illness would continue to occur while establishments prepare for HACCP implementation. Some industry commenters said they were ready to implement HACCP immediately and expressed concern about whether and when the FSIS inspection force would be prepared to oversee HACCP implementation.

Also, several commenters requested a tiered implementation based on product risk. These commenters suggested that establishments which produce high-risk products, such as slaughter establishments or ground beef processors, be required to implement HACCP first and that establishments which produce low-risk products, such as canning establishments, be required to implement HACCP last.

Also, some commenters were concerned about the proposed phase-in period based on different types of product categories and processes because contaminated meat and poultry are known to come from a variety of sources. Commenters said that requiring establishments to implement HACCP at different times for different processes within an establishment would confuse establishment employees, inspection personnel and consumers. Consequently, these commenters suggested that HACCP be implemented simultaneously by all establishments.

Other commenters disputed the definition of small business used in the proposal. Recommendations for defining a small business included using fewer-than-500-employees definition developed by the Small Business Administration (SBA), using a definition reflecting volume of product or number of animals slaughtered, or using a definition based on the level of sales.

In response to concerns expressed by commenters, FSIS is modifying the implementation schedule for HACCP. The revised implementation schedule is based on the size of an establishment, that is, a business entity producing meat or poultry products at a location. Each establishment is required to implement HACCP simultaneously for all processes, rather than on a process-by-process basis. Large establishments (those having 500 or more employees) are required to implement HACCP 18 months after publication of this final rule. ''Small'' establishments are required to implement HACCP 30 months after publication. The definition of ''small'' establishment has been changed to correspond with SBA's size standards for business entities, and is now an establishment having 10 or more but fewer than 500 employees. A new category of ''very small'' establishments (those having fewer than 10 employees or less than $2.5 million in annual sales) will have 42 months to implement HACCP. All individuals employed on a full-time, part-time, temporary, or other basis at a given establishment must be counted as employees. This requirement corresponds with the SBA definition of employee set forth in 13 CFR 121.404.

FSIS is committed to bringing the Nation's meat and poultry supply under HACCP systems as rapidly as possible. Phasing in HACCP implementation is essential due to the logistical effort required to manage a fundamental change in work processes, roles, and responsibilities for both establishments and FSIS. The revised implementation schedule reflects the readiness of establishments of varying sizes to implement HACCP, the time needed by industry to develop HACCP plans and train employees, and the time needed by FSIS to train its employees.

The principal advantages of the revised implementation schedule are as follows:

1. Large slaughter establishments account for 75 percent of slaughter production and thus, most of the Nation's meat and poultry supply will come under HACCP-based process control one year earlier than originally proposed. Because the greatest risk of contamination with pathogenic microorganisms occurs during this initial stage of production, FSIS considers this a significant improvement over the original schedule in terms of expediting progress on improving the safety of meat and poultry products. The revised implementation schedule also ensures that approximately 45 percent of processed products will be produced under a HACCP system within 18 months. In comparison, only 25 percent of processed products would have been produced under HACCP systems at the 18-month mark based on the proposed implementation schedule.

2. By shifting initial implementation of HACCP from 12 months to 18 months after publication of the final rule, FSIS will have sufficient time to manage the transition to sanitation SOP's in all establishments, which will begin six months after publication of this final rule, and to train FSIS employees to implement HACCP. FSIS does not believe it could manage this transition and successfully implement HACCP in 12 months.

3. Eighteen months will provide ample time for the large establishments to comply. In fact, it is reasonable to assume that many of these establishments may implement HACCP before the deadline.

4. Implementing HACCP on the basis of establishment size will be simpler for both FSIS and establishments and much less disruptive for establishments with multiple processes. Under the proposal, these establishments would have faced multiple implementation dates (e.g., establishments that both slaughter cattle and grind beef).

5. The ''very small'' establishments will have an additional six months to implement HACCP. This will enable FSIS to complete the demonstration projects planned for ''small'' and ''very small'' establishments. The extra time will also ensure the availability of ''off-the-shelf'' HACCP training programs prepared by private or industry-sponsored consultants. Other FSIS implementation aids, such as model HACCP plans, audio, video, or computer training aids, and various publications such as guidelines, notices and pamphlets will have undergone extensive development as well.

Small Business Issues

FSIS recognizes that many smaller establishments lack the familiarity with HACCP that exists already in many larger establishments. Therefore, FSIS is planning an array of assistance activities that will facilitate implementation of HACCP in ''small'' and ''very small'' establishments.

FSIS is developing 13 generic HACCP models for the major process categories, which will be available in draft form for public comment, and in final form, at least six months before HACCP implementation. The generic models are being developed especially to assist ''small'' and ''very small'' establishments in preparing their HACCP plans. Because each HACCP system is developed by an individual establishment for its specific process and practices, the generic models will serve only as illustrations, rather than as

prescriptive blueprints for a specific HACCP plan. They should, however, remove much of the guesswork and reduce the costs associated with developing HACCP plans.

FSIS will also conduct HACCP demonstration projects for ''small'' and ''very small'' establishments during the two-year period following promulgation of this final rule. These projects will be conducted at various sites to show how HACCP systems can work for various products under actual operating conditions. Some of these demonstrations will involve ''very small'' establishments and will address issues unique to those establishments. For instance, how does a HACCP system function in an establishment with only a single employee? Through these demonstration projects, FSIS, State inspection authorities, participating establishments, and the industry at large will gain added understanding of the problems and techniques of HACCP implementation and operation in ''small'' and ''very small'' establishments.

FSIS is making available to ''small'' and ''very small'' establishments various HACCP materials that should assist these establishments in conducting their hazard analyses and developing their HACCP plans. These guidance materials include a ''Guidebook for the Preparation of HACCP Plans'' (Appendix C) and a ''Hazards and Preventive Measures Guide'' (Appendix D). These materials should be particularly useful to ''small'' and ''very small'' establishments that may lack the expertise for conducting hazard analyses and designing establishment-specific HACCP plans.

The ''Guidebook for the Preparation of HACCP Plans'' has been designed to provide ''small'' and ''very small'' establishments with a step-by-step approach for developing a HACCP plan and includes examples and sample forms at each step. The Guidebook can be used alone or in combination with the ''Hazards and Preventive Measures Guide.''

Because the development of an adequate HACCP plan depends on a good hazard analysis, the ''Hazards and Preventive Measures Guide'' develops HACCP Principle No. 1 in much greater detail than does the ''Guidebook for the Preparation of HACCP Plans.'' The hazards guide identifies potential biological, chemical, and physical hazards associated with a variety of raw materials and common ingredients, as well as major processes used in the meat and poultry industry. In addition, the hazards guide contains examples of preventive measures for common hazards and associated critical limits for those measures. Also provided are examples to illustrate approaches to implementing the remaining HACCP principles (e.g., monitoring, corrective actions, records, and verification procedures) for various hazards and critical control points.

FSIS invites comments and suggestions on how it may further ease the transition of ''small'' and ''very small'' establishments to HACCP-based operations.

Training Considerations

Many commenters, including consumer groups, FSIS employees, meat and poultry establishments, and State governments, agreed that proper training in HACCP procedures and plan development is vital for successful HACCP implementation. A number of commenters suggested that joint training sessions be held for FSIS and establishment employees to ensure uniform understanding between inspection personnel and industry. Others suggested that FSIS certify acceptable training sites and courses of study for establishment employees to coincide with government employee training. However, some commenters argued that FSIS should not accredit training programs because to do so would limit the development of training programs.

FSIS agrees that effective training of both FSIS and industry employees is critical to HACCP's success. FSIS also agrees that alternatives are needed to make training practical for various kinds of establishments. With these objectives in mind, FSIS is cooperating with the private sector to ensure that a wide variety of training options are available to industry and FSIS employees. For instance, FSIS is encouraging the International Meat and Poultry HACCP Alliance, national and local trade associations, State and local officials, the State agricultural extension services, and local colleges and universities to help establishments incorporate HACCP into their operations. The implementation conferences, discussed elsewhere in this preamble, will address how to achieve the goal of consistent training for FSIS and industry employees.

Other plans include offering HACCP briefings to industry at many locations nationwide. Each session will be led by FSIS HACCP trainers, will be held during the evening, be open to industry and other interested persons, and include a question-and-answer period. FSIS training sessions will be limited to FSIS and State employees because of complex logistical and cost considerations.

USDA's National Agricultural Library has developed and maintains the HACCP Training Programs and Resources Database. It is accessible via the Internet at ''http://www.nalusda.gov/fnic/foodborne/foodborn.htm'' or ''gopher://gopher.nalusda.gov/11/infocntr/fnic/foodborne/haccp'' and provides listings of available training programs (workshops, satellite conferences, etc.), resources (videotapes, software, manuals, textbooks, etc.), and consultants (individuals and companies). Other Internet servers with HACCP-related information are operated by various firms, governments, organizations, and academic institutions.

Several meat and poultry establishments also commented on funding for HACCP training, suggesting that FSIS or State inspection programs fund establishment employee HACCP training. FSIS is making every effort to assist establishments in making the transition to HACCP. However, each establishment will be responsible for training its employees.

Mandatory Versus Voluntary HACCP

Most commenters supported the FSIS proposal to make HACCP mandatory in all meat and poultry establishments. However, some commenters requested that HACCP be voluntary rather than mandatory to alleviate economic burdens, especially on small businesses. Commenters further suggested that, at such time as a voluntary HACCP program proved successful, FSIS could mandate HACCP or, alternatively, market forces and advancing technology could be relied on to ensure its broad acceptance in all parts of the meat and poultry industry.

FSIS has determined that a mandatory HACCP program is the only viable option that will effect adequate processing improvements in all establishments throughout the meat and poultry industries. Mandatory HACCP systems are supported by several prominent organizations, including the International Meat and Poultry HACCP Alliance and the American Meat Institute, which petitioned FSIS to initiate rulemaking to mandate HACCP. HACCP is now and has been voluntary; some establishments have it, most do not. The preamble to the proposed rule explained FSIS's conclusion, affirmed by most commenters, that HACCP is the optimal framework for targeting and reducing the many potential, but largely preventable, hazards associated with meat and poultry products. The risks of

foodborne illness associated with meat and poultry products will be minimized to the greatest extent possible only if HACCP systems are implemented in every establishment.

HACCP From Farm-to-Table

A large number of commenters requested that HACCP be required throughout all phases of food production, from the farm to the consumer. These commenters asserted that HACCP plans could be developed by producers, slaughterers, processors, retailers, food service operators, and restaurants to assess and mitigate food safety risks. Furthermore, many commenters claimed that the majority of foodborne illness cases can be attributed to mishandling at the consumer level and FSIS should therefore strengthen consumer education as well as require HACCP.

There is widespread agreement that ensuring food safety requires taking steps throughout the farm-to-consumer continuum to prevent hazards and reduce the risk of foodborne illness. FSIS is encouraging the active development of food safety measures to minimize public health hazards in animals presented for slaughter. A description of these farm-to-table efforts is discussed earlier in this document.

Total Quality Control (TQC) Establishments and HACCP

One commenter requested that establishments currently operating under the TQC provisions (9 CFR 318.4(c) and, 381.145(c)) be allowed to continue to operate under modified hours. If this is not the case, establishments currently under TQC will incur considerable overtime costs. The commenter asked why, if HACCP represents an improvement over TQC, the establishment operating under HACCP should require more inspection coverage than one operating under current TQC provisions.

This final rule does not alter current policies and practices regarding inspectional coverage and overtime charges in establishments operating under FSIS-approved TQC systems. HACCP is a safety-oriented system of process control that addresses food safety hazards differently than any current FSIS inspection systems, including TQC. Because TQC systems address considerations unrelated to safety, inspection practices developed by FSIS in connection with TQC may or may not be applicable to the implementation of HACCP.

Freedom of Information Act Concerns

Most commenters stated that HACCP records should not be available to requestors through the Freedom of Information Act (FOIA). Some said HACCP records should be used for verification only and should not be included in government files. Others also suggested that access to records by FSIS inspection personnel be restricted to records that are necessary for HACCP compliance monitoring, such as hazard analyses, HACCP plans, CCP monitoring records and corrective action documentation. Other commenters wanted to prohibit FSIS personnel from copying or removing any records from the establishment. Some commenters requested that HACCP records be generally available to the public.

In the preamble to the proposed regulation, FSIS stated that, as a preliminary matter, at least some elements of HACCP plans and monitoring records could be classified as trade secrets or commercial confidential information and may be protected from public disclosure under exemptions provided by FOIA and USDA and FSIS regulations promulgated pursuant to FOIA. FSIS specifically invited comment on the issue of public disclosure of HACCP records and on whether FSIS has any discretion about the releasability of HACCP records that it has in its possession.

Recordkeeping is critical to the successful functioning of HACCP systems in meat and poultry establishments. FSIS will have access to HACCP records and any other records FSIS regulations require. While the records required by this final rule are clearly within the establishment's domain and ownership, FSIS will have access to them. These records, and FSIS access to them, are necessary to effectuate a mandatory system of preventive controls to achieve food safety.

FSIS will continue to make use of documentation to which it has access when necessary to evaluate the operations of official establishments. Inspection personnel will normally review the records at establishments as part of routine HACCP oversight activities. When inspection personnel suspect that an establishment's HACCP system is not operating correctly, they will copy appropriate portions of establishment records, as needed, for further evaluation and possible enforcement action.

An establishment will not ordinarily be required to submit copies of HACCP plans, verification documents, or day-to-day operating records to FSIS. Consequently, FSIS will not normally possess establishment records that may be of a proprietary nature and the issue of whether they are releasable under FOIA should not arise.

Copies of establishment HACCP records may, however, be acquired by inspection personnel to document enforcement actions or otherwise assist FSIS in carrying out its responsibilities. The release by FSIS of information about establishments and their operations is governed by the FOIA. This statute requires Federal agencies to make available to the public agency rules, opinions, orders, records, proceedings, and information concerning agency organization and operations. FOIA provides exemptions from public disclosure for various kinds of information, including information concerning trade secrets and confidential commercial or financial information, and information compiled for law enforcement purposes, the release of which would be prejudicial or harmful to law enforcement or to the privacy rights or safety of individuals.

The FOIA disclosure exemption that is most likely to be relevant is that covering trade secret and confidential, commercially valuable information. FSIS's experience in meat and poultry inspection, its experience with HACCP, and its understanding from the cost-benefit modeling and other studies undertaken in the preparation of these regulations is that HACCP plans will take each establishment some time and money to develop, and will be considered by the establishment to be confidential. It follows that some HACCP plans will include confidential, commercially valuable information, meeting the definition of ''trade secret.'' Plans that incorporate unique time-and-temperature regimens to achieve product safety, or other parameters that are processor-specific and that are the result of considerable research and effort, will ordinarily meet this definition.

Moreover, a plan is valuable to the establishment that produces it for no other reason than that it took work to write. The equity in such a product is not readily given away to competitors. FSIS also knows from its own experience that establishment configurations tend to be unique to individual establishments, or at least have unique features. While generic plans will have great utility in many circumstances, they serve primarily as models for establishments to develop their own plans. Establishments will still have to expend time and money to tailor HACCP to their individual

circumstances. Thus, at least some HACCP plans or other records will include information to which FSIS has access but which FSIS will not be required to disclose publicly under FOIA.

It should be noted, in this regard, that FOIA is not a confidentiality statute, but has as its primary purpose the assurance of the public's right of access to Government information. Agencies must grant requests that ''reasonably describe'' information sought in agency files that is not exempt from mandatory disclosure. For this reason, FSIS understands that it cannot make promises of confidentiality that exceed the permissible boundaries established under FOIA.

FSIS Enforcement Authority and Whistleblower Protection

A large number of commenters requested that FSIS endorse enforcement tools contained in the proposed Family Food Protection Act (H.R. 1423, S. 515), including strengthened authority to refuse or withdraw inspection from official establishments, assessment by the Secretary of civil penalties for violations of the inspection laws, and protection of ''whistleblowers'' from harassment, discrimination, prosecution, and liability. Within the meaning of the proposed legislation, whistleblowers are employees or other persons who assist or demonstrate an intent to assist USDA in achieving compliance with the laws and regulations, refuse to violate or assist in violating the law, or are involved in commencing or testifying in a legal proceeding conducted by USDA.

FSIS has determined that, while additional legislative authority would be helpful in certain areas, it is not needed to implement HACCP and the other requirements established in this final rule.

As to whistleblower protection, many comments urged that these regulations include such protection for employees of meat and poultry slaughtering or processing establishments. Whistleblower protection is designed to protect workers from being fired or otherwise discriminated against for revealing wrongdoing by their employers. The wrongdoing in this case would presumably involve the forced falsification of HACCP records or other interference with proper operation of the HACCP system.

One concern raised by these commenters and others about the credibility of a HACCP system is that important records can be falsified. It is alleged that, without whistleblower protection, it is much less likely that FSIS will know about falsifications. It was also suggested that there is a need to encourage and protect employees who report food safety problems or other violations of the inspection laws.

While FSIS is confident that it can detect falsification in the course of its routine reviews of establishment records, coupled with in-plant observations, FSIS also expects that, as is now the case, it will be alerted by establishment employees to possible wrongdoing even in the absence of whistleblower protection. FSIS has relied on information provided by employees of the regulated industries for many years. From time to time, information is provided with an expectation that the identity of the informant will be kept confidential. FSIS provides this protection, to the extent possible. This policy has been effective.

As a legal matter, FSIS is not empowered by the FMIA and PPIA to build explicit whistleblower protection into the regulations. In contrast to the explicit statutory whistleblower protection accorded Government employees, the FMIA and PPIA do not provide for whistleblower protection for industry employees of the kind suggested by some commenters, and no such explicit protection is included in the final rule.

FSIS believes, however, that certain features of the HACCP regulations being adopted and the manner in which FSIS will inspect meat and poultry establishments compensate for the lack of formal whistleblower protection, for purposes of ensuring food safety. Most importantly, each establishment will be required to document, through records kept by establishment employees, that the critical limits required to ensure food safety are being met and when a failure occurs, proper corrective action is taken. The failure to document safety-related failures and to take necessary corrective action violates HACCP regulations and the establishment will be subject to appropriate regulatory action. Moreover, the falsification of required HACCP records is a serious violation of Federal criminal law and will be investigated and pursued aggressively by FSIS.

Establishments that conscientiously implement HACCP will, in the course of normal operations, support employee reports of HACCP deviations or other potential hazardous processing conditions and take immediate corrective action. HACCP systems in which employees with HACCP responsibilities are prevented or deterred from carrying out their responsibilities will be considered inadequate, and FSIS will pursue appropriate enforcement action.

By virtue of the extensive presence of FSIS inspectors in meat and poultry establishments and the daily access of FSIS inspectors to HACCP records, FSIS will be able to verify whether problems are being properly documented and addressed and will be able to observe potential food safety problems that establishments have not found or are not confronting in an appropriate manner. FSIS emphasizes that undetected or uncorrected conditions which are likely to cause foodborne illness or injury should be reported immediately to FSIS by any person with knowledge of their existence.

Enforcement and Due Process

A significant number of commenters raised concerns about the level of discretion inspection personnel will have in suspending establishment operations due to alleged deficiencies in either the design or the operation of a HACCP plan. Some urged FSIS to make clear to inspection personnel that such extreme actions are to be reserved only for situations in which continued operation of the establishment presents an imminent public health risk. Others strongly argued that operations should be suspended or inspection withdrawn when an establishment fails to comply with any HACCP requirements. Clarification was requested regarding the imposition of penalties and, specifically, what circumstances would warrant suspension of operations or withdrawal of inspection.

Generally, the nature of the enforcement action taken will vary, depending on the seriousness of the alleged violation. Minor violations of the HACCP requirements may be recorded by Agency personnel to determine establishment compliance trends. Minor violations may also result in intensified inspection to ensure that there is no pattern of noncompliance and that there is no underlying food safety concern.

Conversely, serious, repeated, or flagrant violations will result in immediate regulatory action, such as stopping production lines; applying ''U.S. Rejected'' tags to involved equipment, lines, or facilities; retention of product, and suspension or withdrawal of inspection. Because of the importance of recordkeeping to the functioning of HACCP systems and the production of foods that are safe for human consumption, FSIS views recordkeeping as a serious matter with potentially grave implications if records are not properly maintained or are falsified.

Many commenters were troubled by what they perceived to be limited procedural due process afforded to establishments when faced with the suspension of inspection due to a finding that the HACCP plan is inadequate. FSIS agrees that all findings of inadequacy should be sound scientifically and legally, and that suspensions should not be invoked in an arbitrary manner. The optimal system would provide an appropriate level of protection to establishments without unnecessary delay, especially where no factual dispute is likely.

Based on the comments received on this issue, FSIS has decided not to finalize the proposed Rules of Practice at this time. FSIS is interested in receiving comments and suggestions on enforcement, alternative dispute resolution, and due process issues, and has included these topics for discussion at the implementation conferences. On the basis of the conference discussions, FSIS will complete any required rulemaking covering these issues prior to the first implementation date for HACCP.

The Final Rule

Reorganization of HACCP Regulatory Text

FSIS has reorganized the codified regulatory text proposed in the Pathogen Reduction/HACCP proposal and reworded a number of the provisions. These changes have been made in response to comments received on the proposal, for the sake of greater clarity and ease of use, and to conform with FSIS's planned reorganization and consolidation of all its meat and poultry inspection regulations. In general, the final HACCP regulations are more streamlined than the proposed provisions, organized in a more logical form, and less prescriptive than the proposed regulations. Also, as part of the FSIS and FDA effort to adopt a common approach to food safety (described in the January 1996 National Performance Review document ''Reinventing Food Regulations''), FSIS has made changes to the proposed regulatory text, where applicable, to be consistent with FDA's final rule on HACCP systems for seafood (60 FR 65096; December 18, 1995).

To the extent possible, the HACCP requirements for both meat and poultry products have been consolidated in a new part 417.

Requirements affecting grants or refusals of inspection have been moved to a new § 304.3 and a new § 381.22.

FSIS received approximately 7,500 written and many oral comments on the proposed rule from meat and poultry slaughter operations, processors, retailers, trade and other associations, consumer advocates, the scientific and public health community, Federal and State government agencies and foreign governments, employees, and other interested parties. While a majority of these commenters supported the proposal to require adoption of HACCP by meat and poultry establishments, they differed widely regarding plan development, implementation, and related issues. Comments on the specific proposed regulatory requirements and FSIS's responses, follow.

HACCP Systems as a Condition of Receiving Inspection

Proposed § 326.7(a)(2) and § 381.602(a)(2) would have permitted the issuance of a grant of inspection concurrent with a new establishment's development and validation of its HACCP plan. This provision is confusing because it is unclear how an establishment can develop and validate its HACCP plan ''concurrent'' with the granting of inspection when the HACCP plan can only be validated on the basis of commercial operations and the establishment can operate commercially only under inspection. Therefore, it would be impossible for an establishment to validate a HACCP plan prior to receiving a grant of inspection, as proposed. A number of commenters noticed this difficulty and requested that establishments be allowed a reasonable amount of time under commercial production to validate their HACCP plans.

Commenters also disagreed with the proposed HACCP plan development timetable for new establishments or establishments producing new products or those conducting product test production runs. Some said that new establishments and establishments producing new products or conducting test runs subsequent to the applicable HACCP effective date should have at least six months or up to two years to finalize HACCP plans. Others said that all HACCP plans should be developed before start-up with revisions allowed within a reasonable period.

FSIS is in basic agreement with these comments and is revising the basic procedures for granting inspection to allow establishments time to validate their HACCP plans. The provisions in §§ 304.3(b) and 381.22(b) require that any new establishment conduct a hazard analysis and develop a HACCP plan prior to being issued a conditional grant of inspection. The establishment must validate its HACCP plan within 90 days after the conditional grant of inspection is issued. After FSIS has determined that the establishment has validated its HACCP plan, a permanent grant of inspection will be issued. An establishment already receiving inspection may produce a new product for distribution only if it has developed a HACCP plan applicable to the product and validates the plan within 90 days after beginning production of the product.

FSIS is requiring that new facilities and products be covered by a HACCP plan at the time commercial production begins. Establishment management is expected to consider development of HACCP systems as part of essential pre-production decisions for new operations. Establishments are also expected to modify their HACCP plans as needed based upon experience and reported results. FSIS has determined that no start-up time is needed in these instances since the establishment will not be experiencing any transition from an old system to a new processing system.

FSIS is considering what further changes may be necessary in the procedures for granting and inaugurating inspection at official establishments to better accommodate HACCP-oriented inspection. FSIS plans to publish a notice of proposed rulemaking on this matter in the near future.

Definitions

Proposed §§ 326.1 and 381.601 have been combined, streamlined, and redesignated as § 417.1. Thirteen proposed definitions were determined to be commonly understood or unnecessary and have been removed. Of the seven definitions remaining, the definitions for ''critical control point,'' ''critical limit,'' ''HACCP system,'' and ''responsible establishment official'' have been clarified. For example, the definition of ''critical control point'' includes the phrase ''as a result'' to indicate that the prevention, reduction, or elimination of a food safety hazard occurs because of action taken at the critical control point. The definition of ''responsible establishment official'' has been expanded to include the individual with overall authority or a higher level official of the establishment.

The revised definitions are consistent with those promulgated in FDA's final rule on HACCP systems for seafood. For example, FSIS has added a new definition to § 417.1 for the term ''process-monitoring instrument.'' This term is defined as ''an instrument or device used to indicate conditions during processing at a critical control

point.'' FSIS determined that this definition would be helpful to establishments developing HACCP plans.

Hazard Analysis and HACCP Plan

The proposal required each establishment to develop and implement a HACCP plan which incorporated the seven HACCP principles. A hazard analysis was to be conducted to identify biological, chemical and physical hazards and a list of steps in the process where potentially significant hazards could occur and the preventive measures to be taken were to be identified.

Provisions relating to the hazard analysis and development of the HACCP plan were proposed as §§ 326.2 and 381.602, ''Development of HACCP Plan,'' §§ 326.3 and 381.603, ''HACCP Principles,'' and §§ 326.4 and 381.604, ''Implementation of the HACCP Plan.'' These provisions have been modified and incorporated into § 417.2.

Several commenters argued that in the event the hazard analysis identified no significant hazards, the establishment should be exempt from developing HACCP plans and operating under a HACCP system. Commenters identified lard and meat flavoring manufacturers and canning operations as examples of establishments that may identify no hazards.

To clarify the concept of potentially significant hazards, and to be consistent with the FDA final rule on HACCP systems for seafood, the final rule requires each establishment to conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process. A food safety hazard that is reasonably likely to occur is defined as one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

FSIS agrees that if an establishment's hazard analysis reveals no hazards, then no HACCP plan would be required. However, FSIS is currently unaware of any meat or poultry production process that can be deemed categorically to pose no likely hazards. With regard to the lard and meat flavoring examples, FSIS believes that reasonably likely biological and physical hazards requiring control measures exist in establishments manufacturing these products and that, therefore, HACCP plans are required.

FSIS agrees that the microbial hazards associated with canned meat and poultry products are eliminated by complying with the regulations in 9 CFR §§ 318.300–311 and 381.300–311. These regulations are based on HACCP concepts and provide for the analysis of thermal processing systems and controls to exclude microbial hazards. Accordingly, the final rule provides that HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the canning regulations. However, because the current regulations exclusively address microbial hazards, processors of canned meat, meat food and poultry products must develop and implement HACCP plans to address chemical and physical hazards that are reasonably likely to occur.

The current canning regulations contain numerous prescriptive features, including extensive FSIS involvement in the decisionmaking process, that are inconsistent with the philosophy underlying HACCP. In the advance notice of proposed rulemaking ''FSIS Agenda for Change: Regulatory Review'' (60 FR 67469; December 29, 1995), FSIS stated its intention to convert the canning regulations to performance standards, which are more consistent with HACCP. Until changes in the canning regulations are finalized, canning establishments do not have to address microbial hazards in their HACCP plans.

The provisions of proposed § 326.3(a), (a)(1), and (a)(2), and § 381.603(a), (a)(1), and (a)(2) relating to process flow charting and the identification of intended uses and consumers of the product have been combined in the final rule into § 417.2(a)(2).

Proposed §§ 326.2(b) and 381.602(b) would have required that any HACCP plan be developed with assistance of a HACCP-trained individual employed by the establishment, that the individual's name and resume be on file, and that the individual meet other prescriptive requirements. These requirements have been removed in response to criticism expressed in comments received and for reasons given below in the discussion of § 417.7. The new § 417.2(a)(1) permits someone other than an establishment employee to conduct the hazard analysis.

Proposed §§ 326.3(a) and 381.603(a) would have required a hazard analysis to identify any biological (including microbiological), physical, or chemical hazards. In § 417.2(a)(3), FSIS lists ten areas that should be considered by an establishment when performing its hazard analysis. These ten areas are: natural toxins; microbiological contamination; chemical contamination; pesticides; drug residues; zoonotic diseases; decomposition; parasites; unapproved use of direct or indirect food or color additives; and physical hazards. This list of possible hazards provides more complete guidance to establishments conducting a hazard analysis; it responds to industry comments criticizing as ''vague'' the proposed definition of hazard; and it is also consistent with the list of hazards in FDA's final rule on HACCP systems for seafood.

Proposed §§ 326.2(a) and 381.602(a) would have required that establishments develop, implement, and operate a HACCP plan for each process conducted by the establishment, and provided a list of process categories subject to this requirement. Section 417.2(b) provides that each establishment develop and implement a HACCP plan covering each product produced, whenever its hazard analysis reveals one or more food safety hazards that are likely to occur. This requirement is substantively the same as the proposal.

Section 417.2(b)(1) provides a revised list of process categories, while § 417.2(b)(2) states that a single HACCP plan may encompass multiple products within a single processing category, if the hazards, CCP's, and critical limits are essentially the same, and as long as any plan features that are unique to a specific product be clearly set out in the HACCP plan and observed in practice. For example, an establishment's HACCP plan for the processing of cooked sausage might cover bologna, knockwurst, and frankfurters that the establishment produces.

Proposed §§ 326.2(d) and 381.602(d) would have required that the HACCP plan be developed in two stages, both to be completed six months prior to the phase-in date of the applicable process category or upon application for inspection or when a new process is ready for implementation. FSIS has eliminated these requirements because they are impractical.

Proposed §§ 326.2(d)(1) and 381.602(d)(1) would have required that every HACCP plan be in a format similar to the NACMCF and FSIS generic models. FSIS agrees with those commenters who found this proposed requirement to be unnecessary and too prescriptive, and has not included this requirement in the final rule.

Proposed §§ 326.3 and 381.603 set forth the seven HACCP principles accompanied by the corresponding requirements establishments must meet when developing HACCP plans. In response to comments that the detailed

provisions were unnecessary, FSIS has set forth in § 417.2(c) a simplified list of requirements, based on the seven HACCP principles, to be met by establishments when developing HACCP plans. The proposed requirements remain, except for the following additions, unchanged.

Two subparagraphs have been added to new § 417.2(c)(2), clarifying the requirements for the identification of CCP's within a HACCP plan. This new section requires that establishments list in their HACCP plan the CCP's for each of the identified food safety hazards, including, as appropriate: (1) CCP's designed to control food safety hazards that could be introduced in the establishment, and, (2) CCP's designed to control food safety hazards that may have been introduced into the product before, during and after its entry into the establishment. In response to comments objecting to the proposed requirement for establishments to use a decision tree in identifying CCP's (proposed § 326.3(b) and 381.603(b)), this requirement has been removed from the final rule.

Proposed §§ 326.4 and 381.604 would have required that a responsible establishment official, formerly defined as ''the management official located on-site at the establishment who is responsible for the establishment's compliance with this part,'' review, approve, and sign the HACCP plan. Section 417.2(d)(1) requires that the HACCP plan be signed by the responsible establishment official, defined as the individual with overall authority on-site or a higher level official of the establishment, possibly off-site. Further, in § 417.2(d)(2), FSIS is correcting an oversight in the proposal by requiring that the HACCP plan must be signed and dated upon initial acceptance by the establishment and at any time the plan is modified. The proposal required that the responsible establishment official sign the plan upon completion of the hazard analysis and the development of the HACCP plan. The HACCP plan must also be signed and dated at least once each year after the required reassessment.

Finally, FSIS explicitly states its statutory authority to enforce the HACCP regulations under § 417.2(e), providing that if an establishment fails to develop and implement a HACCP plan or to operate in accordance with the requirements of this part, the products produced by the establishment may be deemed adulterated.

Corrective Actions

Proposed §§ 326.3(e) and 381.603(e) would have required that each establishment develop corrective actions to be taken when there is a deviation from an established critical limit. Under the proposed provisions, if a deviation were found, the establishment would describe the steps taken to identify and correct the deviation, determine how noncompliant product would be handled, ensure that no safety hazards exist after the corrective actions are taken, and define measures to prevent recurrence. Further, this section required that the establishment determine whether its HACCP plan required modification and, if so, to modify the plan.

Many commenters stated that establishments should be empowered to make decisions on product safety. Commenters generally maintained that the establishment should have primary responsibility for setting the CCP's and critical limits and for taking corrective action when there is a deviation. Inspectors should verify the overall effectiveness of the HACCP plans, including the corrective actions taken by establishments. A number of commenters were concerned about the possibility that FSIS might take action on a product if a critical limit in the establishment's HACCP plan was not met, even if the establishment were taking corrective action under the plan. Commenters felt that this action by FSIS would be unwarranted. An additional concern was that the potential for this type of problem would be compounded if the establishment set a critical limit more restrictive than necessary for food safety to meet quality standards, for example, a higher cooking temperature than necessary to produce a pathogen-free product.

The establishment must take corrective action for any deviation from a set critical limit. FSIS will verify that the establishment has taken appropriate corrective action as specified in their HACCP plan. If an establishment fails to take corrective action as specified in its HACCP plan, FSIS may find that the HACCP system is inadequate pursuant to § 417.6(c). FSIS agrees that establishments should be empowered to make decisions regarding product disposition in accordance with corrective actions specified in their HACCP plans. FSIS is requiring (§§ 417.2(c)(5) and 417.3) that establishments describe in their HACCP plans the corrective actions that will be taken if a critical limit is not met and assign responsibility for taking corrective action. Corrective actions must ensure that no product that is injurious to health or is otherwise adulterated as a result of the deviation enters commerce, that the cause of the deviation is identified and eliminated, that the CCP will be under control after the corrective action is taken, and that measures to prevent recurrence are established.

FSIS recognizes that preestablished corrective actions may not cover every contingency and that unforeseen hazards or deviations may occur. Thus, § 417.3 of the regulations provides a series of steps to be taken in such situations. These steps include segregating and holding affected product and conducting a review to determine the acceptability of the product for distribution, ensuring that any adulterated product or product otherwise injurious to health does not enter commerce, and reassessing HACCP plans to determine if any modification is needed.

Validation, Verification, and Reassessment

Proposed §§ 326.3(g) and 381.602(g) would have required that establishments develop procedures for HACCP plan validation by an adequately trained individual, and set forth the related requirements. Proposed §§ 326.4 and 381.604 further detailed the validation requirements, stating that during the validation period, establishments shall conduct repeated verifications of the plan, hold frequent meetings with Program employees, and review records generated by the HACCP system. Under the proposal, establishments were to modify their HACCP plan following any ingredient change, product reformulation, manufacturing process or procedure modification, equipment change, or any other such change. Revalidation of an establishment's HACCP plan would have been required whenever significant product, process, deviations, or packaging changes required modification of the plan.

Many commenters expressed confusion about the meaning of the terms ''validation'' and ''verification'' as used in the proposed rule. The question of who will be responsible for validating HACCP plans was raised by a number of commenters. Some requested a clearer definition of the term ''validation'' as well as clarification of who will approve and verify a HACCP program. Particular concern was expressed about what role local inspection personnel will have in the HACCP plan development and approval process. Some said that FSIS should assume more responsibility for approving HACCP plans through a prior approval system; others argued that no formal acceptance or prior approval of

HACCP plans by FSIS should be required.

In the final rule, FSIS has clarified the concepts of ''validation'' and ''verification'' by delineating the responsibilities of FSIS and establishments in separate codified sections. The initial validation, ongoing verification, and reassessment procedures to be followed by establishments are presented in § 417.4 and FSIS's verification procedures are presented in § 417.8.

Because prior approval of HACCP plans by FSIS would be contrary to redefined roles and responsibilities inherent in the HACCP philosophy, FSIS will not approve or validate HACCP plans before an establishment implements its HACCP system. Each establishment will be responsible for developing its HACCP plan and ensuring its adequacy.

Commenters opposed to FSIS involvement in plan validation offered two suggestions: (1) establishments could use an independent third party, such as a processing authority or consultant with HACCP expertise to validate HACCP plans or (2) HACCP-trained establishment employees could validate plans.

FSIS concurs. Establishments will be required to have validated plans and may use independent consultants, process authorities, or establishment employees trained in accordance with § 417.7 for plan development and validation. FSIS is not prescribing that any particular validation method be used.

Some establishments may choose to use the services of laboratories or processing authorities to validate their CCP's, especially if there are questions about the effectiveness of traditional controls, or if they are considering use of controls which have not been previously validated, such as cooking time/temperature combinations. However, many establishments will choose to rely on CCP's that have been scientifically validated and reported in the literature. In either case, FSIS believes that requiring individual establishments to validate their HACCP plan ensures that the CCP's and the overall HACCP plan work as intended in the establishment to reduce or eliminate hazards and prevent the production of unsafe food.

One industry member observed that his company defines validation as documenting that a critical control point eliminates or effectively addresses microbiological hazards.

FSIS agrees that validation includes documenting that critical control points effectively address relevant hazards, including such microbiological hazards as *E. coli* O157:H7, *Salmonella,* and *Campylobacter,* but emphasizes that validation is more than just the accumulation of microbiological data verifying each CCP. It involves scientifically demonstrating that a HACCP system as designed is effective in controlling the food safety hazards identified through the hazard analysis.

One academic commenter advocated inoculation studies using pathogens as the best way to assure that a HACCP plan will effectively control microbiological hazards. Such studies would be conducted before HACCP implementation and should be aimed at demonstrating that selected CCP's are appropriately monitored to control specific pathogens. The studies would be performed under controlled conditions in off-site laboratories or pilot establishments. One advantage of this approach, according to the commenter, would be to permit validation studies to be conducted by trade associations and other industry groups on a collective basis in a way that could benefit both large and small establishments.

FSIS agrees that validation of CCP's is an important part of HACCP plan validation, and that laboratory inoculation studies as suggested by the commenter can make an important contribution in appropriate cases. Inoculation studies can demonstrate the effectiveness of particular controls in addressing particular hazards under experimental conditions, and can produce data that can be relied upon by many establishments to support plan validation. In no case, however, would a laboratory inoculation study or any laboratory study be sufficient by itself to validate a HACCP plan. An important element of validation is the identification or development of data which show that the establishment can apply the process or control to get the anticipated effect under actual in-plant operational conditions. For some well-established, widely used processes or technologies, in-plant validation can be accomplished by combining existing scientific data from laboratory studies, the scientific literature, or other sources, with the results of commercial trials using recognized protocols. Where processes are well-documented in the scientific literature, it is not necessary to require inoculation studies or any other research effort as part of the validation process. However, an establishment introducing a new technology, applying standard technology in an unusual way, or lacking experience with a technology, would have to undertake more extensive scientific and in-plant validation of its HACCP plan under commercial operating conditions.

Data assembled to validate a HACCP plan are usually of two types: (1) theoretical principles, expert advice from processing authorities, scientific data, or other information demonstrating that particular process control measures can adequately address specified hazards, such as studies establishing the temperatures necessary to kill organisms of concern; and (2) in-plant observations, measurements, test results, or other information demonstrating that the control measures, as written into a HACCP plan, can be operated within a particular establishment to achieve the intended food safety objective. This means that the data used to validate a HACCP plan may be derived from various sources, including the scientific literature, product testing results, experimental research results, scientifically based regulatory requirements, FSIS guidelines, computer-modeling programs, and data developed by process authorities. The nature and quantity of information required to validate a HACCP plan will vary depending on factors such as the nature of the hazard and the control measures chosen to address it.

FSIS believes that validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual early experience in implementing the HACCP plan. This is because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that this establishment can implement it and make it work. For example, steam vacuuming has been scientifically demonstrated to be effective in removing visible contamination and associated bacteria from carcass surfaces. A slaughtering establishment using the technology as a control measure at a CCP, however, would still have to demonstrate its ability to use the technology effectively at the CCP.

Establishment verification is intended to show that the HACCP system is actually working effectively on a day-to-day basis. Verification also includes repeatedly reviewing and evaluating the various components of the system. Verification activities include checking the adequacy of the critical limits; reviewing monitoring and recordkeeping procedures (as distinguished from monitoring the CCP's), and evaluating the adequacy of corrective actions.

One consumer group stated that FSIS should require that establishments identify the specific microbiological hazards that their HACCP plans are

designed to address, and validate and verify the plans using pathogen-specific testing to ensure that establishments control these hazards.

FSIS agrees that establishments must identify the specific microbiological hazards their HACCP plans are designed to address and that the plan must be initially validated and continually verified as effective in addressing those hazards. FSIS also agrees that pathogen-specific testing can play an important role in both initial validation and verification.

For example, in validating the adequacy of a beef slaughter HACCP plan addressing the hazard posed by *E. coli* O157:H7, laboratory inoculation studies involving pathogen-specific testing could be used to validate the effectiveness of the specific control measures that an establishment is considering for incorporation in its HACCP plan. As discussed above, to complete the validation of the control measures for *E. coli* O157:H7, the establishment would also be required to demonstrate that the experimentally validated measures can be successfully carried out under actual operating conditions, but, for *E. coli* O157:H7 on going verification is unlikely to include in-plant testing for the pathogen due to its relatively infrequent occurrence.

In-plant testing to verify a control measure may be appropriate with other pathogens, however. For example, a poultry slaughter establishments would be required to validate and verify the effectiveness of its HACCP plan in addressing the hazards posed by *Salmonella* and *Camplylobactor.* Depending on the nature of the control measures the establishment selects, in-plant pathogen testing could be a necessary and practical component of an on-going verification for these pathogens as they are present in sufficient numbers to make in-plant testing feasible and informative. FSIS intends to work closely with industry at large and with specific establishments in particular to ensure that HACCP plans are adequately validated and verified for microbial pathogens of public health concern.

Verification of HACCP plans by establishments is designed to demonstrate that the HACCP plan is accomplishing process control and resulting in the production of safe food on a continuing basis. Verification is distinct from ongoing establishment monitoring, which is designed to provide a record showing that the written HACCP plan is being followed. Establishment verification activities should provide practical results specific to the operation of its HACCP plan, and can include review of CCP-monitoring records; review of corrective action records; calibration of process-monitoring instruments; collection of either in-line or finished product samples for microbiological, chemical, or physical analysis; and direct observations of monitoring activities and corrective actions. Frequencies for conducting verification activities will vary, depending on various factors, such as the type of process and volume of products, the results of prior verification activities, consistency of conformance with the HACCP plan, how deviations are handled, and the results of any sampling activities.

The record-verification could include determining whether the critical limit for the CCP, as called for in the HACCP plan, matches the critical limit indicated in the records. The verification could also involve checking to assure that the critical limit as set in the establishment's HACCP plan is adequate to prevent a hazard. For example, this check might involve determining whether the random variations inherent in any process are within the limits (temperature ranges, physical contamination) set for the process, and that the critical limit is never exceeded or, further, that the probability that the critical limit might ever be exceeded is extremely low.

The visual observations and records verification could include, in addition to seeing that the records are being properly maintained, assuring that corrective actions have been taken whenever any deviations have occurred and that, when taken, the corrective actions were sufficient to solve the problem.

FSIS has made two minor changes from the proposed validation and verification requirements. First, FSIS has removed the proposed requirement that during validation an establishment hold frequent meetings with Program employees. FSIS recognizes that frequent meetings may not be necessary or appropriate. Also, § 417.4(a)(2) provides that the establishment's ongoing verification activities include direct observation of monitoring activities and corrective actions, review of records, and calibration of process-monitoring instruments. An establishment calibrates its monitoring instruments to determine whether they are functioning properly.

Reassessment

The proposed rule would have required that establishments revalidate the HACCP plan whenever significant product, process, deviations, or packaging changes required modification of the plan.

A consumer group stated that establishments should be required to examine their plans on a regular basis, whenever any new equipment is introduced, new employee training is implemented, or for any other significant change in the processing environment. The commenter further stated that revalidation should be required of establishments every three years even if there has been no significant change in operations. Most commenters generally agreed that the industry has the primary responsibility to review and modify HACCP plans when necessary and that the review and modification process should be flexible.

FSIS agrees that HACCP plans should be reexamined periodically and that the review and modification process should be flexible. The final rule requires that each establishment reassess the adequacy of its HACCP plan at least annually, and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (§ 417.4(a)(3)). These changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The reassessment must be completed by an individual trained in accordance with § 417.7. Immediate modification of the plan is required if the reassessment reveals that the plan is no longer adequate to meet the requirements of part 417. FSIS is also requiring that an establishment that does not have a HACCP plan reassess its hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists.

FSIS considers annual reassessment appropriate because, as commenters have noted, HACCP plans are dynamic and evolving. HACCP plans may be modified several times during the months after they are first implemented. Further, repeating the entire validation process may not be necessary to ensure that the HACCP system is functioning correctly after modification.

The intent of this provision is to provide for periodic modification of the HACCP plan to ensure that it is continuously effective in controlling and preventing food safety hazards. This intent is supported by comments received from various sectors of the public. The commenters tended to see periodic review and modification of HACCP plans as both desirable and

expected and that periodic review and modification would allow the establishment to apply its experience to continually improve process controls.

FSIS believes that ''reassessment'' encompasses the different types of evaluation, from reanalyzing the verification procedures for an updated CCP to repeating the validation procedures set forth in § 417.4, that may be necessary.

FSIS Verification

Verification of HACCP plans is also a regulatory responsibility. FSIS will verify that HACCP plans comply with the requirements of Part 417 and have been validated by the establishment. Potential verification activities by FSIS may include, but are not limited to, sampling activities (targeted and non-targeted, marketplace, rapid screening tests for chemical residues); hands-on verification (organoleptic inspection, use of temperature or other monitoring devices); and review of establishment monitoring records. The frequency of FSIS verification activities will vary, depending on a number of factors such as the establishment's past performance, risk inherent in the processes or products, quantity of product, and likely uses.

A consumer group stated that as part of its verification activities, FSIS should review all pathogen data generated by the establishment to determine the adequacy of the establishment's conclusions regarding pathogen control. FSIS plans to undertake extensive and varied activities to verify that a HACCP plan is working as intended, including review of data generated or relied on by the establishment to validate its HACCP plan.

Proposed §§ 326.7(b) and 381.607(b) set forth FSIS's responsibilities with respect to verification activities. These provisions have been slightly revised for clarity and are consolidated in § 417.8.

Records

Proposed §§ 326.6(b) and 381.606(b) listed the types of records every establishment would have been required to maintain regarding their operations under HACCP. The list included the written HACCP plan, hazard analysis, records associated with CCP monitoring, corrective actions, verification procedures and results, product codes, identity, and slaughter production lot, the dates of the records, and supporting documentation for the various features of the HACCP plan. FSIS also proposed to require a preshipment review of processing and production records associated with the HACCP plan to ensure that the records were complete, that all critical limits were met, and, if applicable, that corrective actions were taken. The review was to be performed by someone other than the person who created the records, preferably by a HACCP-trained individual, or by the responsible establishment official. FSIS considers the preshipment record review a routine verification function under HACCP principle No. 7.

FSIS also proposed that establishments retain all required records on site at all times, except those records concerning monitoring CCP's, corrective actions, and verification procedures were to be retained at the establishment for no less than one year, and for an additional two years at the establishment or other location from which the records could be made available to Program employees.

Regarding the preshipment review of records, several small establishments commented that there may not be a person other than the person who created the record available to conduct the preshipment review. Several large establishments were concerned that a HACCP-trained individual may not be available to conduct the preshipment review. FSIS has modified this requirement by stating that the preshipment review shall be conducted by someone other than the person who produced the records where practicable. Also, FSIS has retained the provision that the review be conducted preferably by an individual trained in accordance with § 417.7 or the responsible establishment official.

Some commenters recommended that FSIS allow the use of electronic or computerized recordkeeping systems to ease the burden of the proposed recordkeeping requirements. In response to these comments, FSIS has added a new § 417.5(d) which provides for the maintenance of data and information on computers, as long as controls are implemented by the establishment to ensure the integrity of the data and signatures.

Commenters also raised concerns regarding proposed record retention requirements, maintaining that keeping HACCP records for a minimum of three years would be excessive. Commenters requested flexibility in deciding how long to retain records; many stated that retention should be based on product shelf-life. In response to these commenters, FSIS has modified this requirement to provide that records required by § 417.5(a)(3) be retained at the establishment for one year if they pertain to slaughter activities or refrigerated products, and for two years if they pertain to frozen, preserved, or shelf-stable products.

To further ease the recordkeeping provisions for establishments, FSIS will permit the off-site storage of records required by § 417.5(a)(3) that are over 6 months old if the records can be made available to Program employees within 24 hours of the request. The records required by § 417.5 (a)(1) and (a)(2), however, are not eligible for off-site storage.

Proposed §§ 326.6 and 381.606 would have provided that records be made available to Program employees. Section 417.5(f) clarifies that all records required by part 417 be available to Program employees for review and copying.

For clarity, FSIS has reworded the recordkeeping provisions to require that the establishment maintain the written hazard analysis and all supporting documentation, the written HACCP and all decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures. Records documenting the monitoring of CCP's and critical limits, corrective actions, verification procedures and results, product code(s), product name or identity, or slaughter production lot must also be maintained. Each record must include the date the record was made. To be consistent with FDA's final rule on HACCP systems for seafood, FSIS has also added a requirement that records relating to the calibration of process-monitoring instruments be maintained.

Training

FSIS proposed two definitions related to training: ''HACCP-trained individual'' and ''recognized HACCP course.'' ''HACCP-trained individual'' was defined as ''a person who has successfully completed a recognized HACCP course in the application of HACCP principles to meat or poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.'' A ''recognized HACCP course'' was defined as ''a HACCP course available to meat and poultry industry employees which satisfies the following: consists of at least 3 days, 1 day devoted to understanding the seven principles of HACCP, 1 day devoted to applying these concepts to this and other regulatory requirements of FSIS, and 1 day devoted

to beginning development of a HACCP plan for a specific process.''

Some commenters thought that defining a HACCP-trained individual was unnecessary, that the role of such a person in operating HACCP systems should be analogous to the role of the processing authority in canning operations.

A few commenters questioned the effectiveness of the proposed three-day training requirement stating it would not sufficiently qualify a person to implement or operate a HACCP system. Some commenters asserted that the detailed course composition with no FSIS certification of courses was inadequate and too rigid. Others insisted that what is needed is a common understanding of the basic principles of HACCP and of how HACCP can be applied to specific processes and establishments, with no FSIS certification of courses.

FSIS has revised the regulations, which are now codified in § 417.7, to simplify the proposed training requirements. The proposed definition and requirements for a HACCP-trained individual have been removed. Section 417.7 requires that individuals performing certain functions must have successfully completed a course in the application of the seven HACCP principles to meat and poultry product processing, including a segment on the development of a HACCP plan for a specific product. Only those individuals who meet the training requirements may perform the following functions:

- Development of the HACCP plan as required by § 417.2(b);
- Reassessment and modification of the HACCP plan as required by § 417.3 and/or § 417.4(a)(3).

The rule has been modified to set a basic standard for HACCP training while preserving the flexibility needed by industry to implement HACCP systems effectively. The provisions of § 417.7 are consistent with FSIS's view that training is central to the success of HACCP, that there are many avenues for HACCP training needs, and that responsible establishment officials are in the best position to determine the training needs for each establishment.

Adequacy of HACCP Plans

The proposed rule stated that a HACCP plan could be found invalid if it does not meet the regulatory requirements, if HACCP records are not being maintained to validate the plan or verify process control under the plan, or if a processing failure results in production of adulterated product.

The provisions of the final rule relating to the criteria for finding a HACCP plan inadequate are essentially the same as in the proposal, except that the term ''invalid'' has been replaced with ''inadequate'' for clarity. Also, the final rule states that a HACCP plan may be found to be inadequate if establishment personnel are not performing tasks specified in the HACCP plan. One change from the proposal concerns the correction of HACCP systems found inadequate because of product adulteration. Under the proposed §§ 326.7(c)(3)(ii) and 381.607(c)(3)(ii), the establishment would have been required to submit to FSIS, among other things, a written plan for chemical or microbiological testing by an external laboratory of finished product produced under the modified HACCP plan to show that the modified plan corrected the problem. The final rule is more flexible because decisions regarding the appropriateness of the HACCP system modifications are made by the establishment.

FSIS will verify that HACCP plans are adequate. The procedure for determining the adequacy of the HACCP plan will not be a one-step process. Instead, FSIS will take a variety of actions including reviewing the HACCP plan and associated records, directly observing the HACCP system in operation, and assessing the adequacy of corrective actions. After a thorough review is conducted, FSIS will determine whether a HACCP plan is adequate. If a plan is found to be inadequate, FSIS will take appropriate regulatory action.

III. Sanitation Standard Operating Procedures

The Proposed Rule

FSIS proposed that all meat and poultry establishments be required to develop, maintain, and adhere to written sanitation standard operating procedures (Sanitation SOP's). The proposal was based on FSIS's belief that effective establishment sanitation is essential for food safety and to successful implementation of HACCP. Insanitary facilities or equipment, poor food handling practices, improper personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. There are direct and substantial links between inadequate sanitation and the contamination of meat and poultry products by pathogenic bacteria. FSIS tentatively concluded that Sanitation SOP's were necessary because they would clearly define each establishment's responsibility to consistently follow effective sanitation procedures and would substantially minimize the risk of direct product contamination and adulteration.

FSIS also had determined that Sanitation SOP's would improve the utilization of FSIS Inspection Program resources by refocusing FSIS sanitation inspection on the oversight of establishment prevention and correction of conditions that cause direct product contamination or adulteration. After Sanitation SOP's were in place, Agency inspection personnel would spend less time enforcing detailed sanitation requirements and directing the correction of problems after they occur. Instead, FSIS inspectors would focus on oversight of an establishment's implementation of Sanitation SOP's and on taking appropriate regulatory action when an establishment's Sanitation SOP's were not properly executed or when product contamination or adulteration was imminent, directly observed, or probably had occurred.

The concepts underlying the proposed requirements for Sanitation SOP's are important and new. In the past, FSIS has not clearly articulated the responsibility every establishment has to ensure that sanitation requirements are met every day, both before and during operations. Although the majority of meat and poultry establishments maintain adequate sanitary conditions, some establishments have significant sanitation problems that can be resolved only through more clearly defining establishment responsibility and accountability for the daily observance of sound sanitation practices.

The proposed requirements for Sanitation SOP's were the result of many years of observations by FSIS of establishment sanitation and management practices. The persistence of insanitary conditions within some meat and poultry establishments was documented in the ''1,000 Plant Review,'' conducted by FSIS between September 1993 and February 1995. This project involved unannounced visits to 1,014 inspected establishments during which operations were observed and deficiencies noted. More than 60 percent of all deficiencies documented by the review involved establishment sanitation. The distribution of sanitation problems was not, however, uniform in the establishments sampled. Fewer than half those establishments visited accounted for 90 percent of the sanitation deficiencies. Data collected through FSIS's Performance Based Inspection System similarly documents that sanitation is the most frequent deficiency noted by inspection personnel in routine establishment visits.

Through analysis of this information, FSIS determined that the difference between establishments with consistently sanitary conditions and those with chronic sanitation deficiencies is often that the better performing establishments have effective quality control and sanitation programs, including written Sanitation SOP's, while the marginal establishments do not. As a means of bringing all establishments to a consistently acceptable level of sanitation, as well as to clarify the respective roles of establishments and FSIS in achieving that goal in each establishment, FSIS proposed that every meat and poultry establishment develop, maintain, and adhere to written Sanitation SOP's.

FSIS proposed that Sanitation SOP's cover the daily preoperational and operational sanitation procedures that the establishment would implement to prevent direct product contamination or adulteration. Additionally, establishments would be required to identify the establishment officials who would monitor daily sanitation activities, evaluate whether the Sanitation SOP's are effective, and take appropriate corrective action when needed. Also, each establishment would be required to make daily records showing completion of the procedures in the Sanitation SOP's, any deviations and corrective actions taken, and maintain those records for a minimum of six months. Further, an establishment's Sanitation SOP's and records were to be made available to FSIS for verification and monitoring. Finally, the proposal provided that any equipment, utensil, room or compartment found by an inspection program official to be not in compliance with the Sanitation SOP's or insanitary would be tagged ''U.S. Rejected,'' and could not be used until it had been reinspected and passed.

FSIS solicited comments on the proposed regulatory requirements for Sanitation SOP's. FSIS also requested comments on how Sanitation SOP's should clarify the responsibilities of establishments and what role inspection personnel should play in authorizing daily startup of operations. Comments also were requested on whether certain Good Manufacturing Practices (GMP's) or other sanitation practices should be mandatory elements of the Sanitation SOP's.

The majority of the comments addressing the proposed Sanitation SOP's provisions expressed support. Many commenters, however, expressed concern about the lack of detail in the proposal regarding the required contents of an establishment's Sanitation SOP's and about how Sanitation SOP's would be enforced by inspectors. The comments, both written and oral, and FSIS's responses are discussed in the ''Comments'' section, which follows the description of the final rule.

The Final Rule

After careful consideration of the comments, FSIS is promulgating requirements for Sanitation SOP's, essentially the same as proposed, though with several changes and additions for both clarity and to grant establishments greater flexibility in meeting the Sanitation SOP's requirements.

As proposed, all inspected establishments shall develop, implement, and maintain written Sanitation SOP's. The Sanitation SOP's shall describe all procedures and establishment conducts daily to prevent direct contamination or adulteration of product(s). FSIS has clarified that Sanitation SOP's also shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s). While the employee responsible for implementation and maintenance of procedures in the Sanitation SOP's may be the employee who actually performs such activities, he or she instead may be the employee in charge of ensuring that the sanitation procedures are carried out. All that is required is that the Sanitation SOP's identify the employee(s) responsible for implementation and maintenance of the procedures in the Sanitation SOP's. The establishment does not need to necessarily identify the employee(s) who will actually perform the sanitation procedures. Also, an establishment's Sanitation SOP's may have more than one employee responsible for implementation and maintenance of sanitation procedures. For example, one employee may be responsible for pre-operational procedures and another may be responsible for operational procedures. The rule provides such flexibility.

Further, FSIS is clarifying in this final rule that establishments must explicitly identify pre-operational sanitation procedures in their written Sanitation SOP's, distinguishing them from sanitation activities to be carried out during operations. This will assist both the establishment and FSIS in identifying which sanitation procedures are to be carried out each day prior to start-up of operations.

FSIS is also requiring that Sanitation SOP's be signed and dated by ''the individual with overall authority on-site or a higher level official of the establishment,'' and that the signature shall signify that the establishment will implement the Sanitation SOP's. This new language grants establishments greater flexibility than did the proposed requirement that ''the establishment owner or operator'' be responsible for implementation of Sanitation SOP's. Additionally, this final rule specifies that Sanitation SOP's must be signed upon initiation and upon any modification.

As in the proposal, the format and content of Sanitation SOP's are not specified in the final regulations. Because there are many types of inspected establishments that will achieve the required sanitary conditions in different ways, this rule gives establishments flexibility to customize their sanitation plans. Each meat and poultry establishment must analyze its own operations and identify possible sources of direct contamination that must be addressed in its Sanitation SOP's.

As proposed, each establishment is required to conduct the pre-operational and operational procedures as specified in the Sanitation SOP's, monitor the conduct of the procedures, and routinely evaluate the content and effectiveness of the SOP's and modify the Sanitation SOP's accordingly. The Sanitation SOP's must be kept current. The establishment must evaluate and modify Sanitation SOP's as needed in light of changes to establishment facilities, personnel, or operations to ensure they remain effective in preventing direct product contamination and adulteration. As upon initial implementation, Sanitation SOP's must be dated and signed by the individual with overall authority on-site or a higher level official of the establishment following any modification.

Also as in the proposal, FSIS is requiring that each establishment initiate corrective action when either the establishment or FSIS determines that Sanitation SOP's or their implementation may have failed to prevent direct product contamination or adulteration. The requirements regarding corrective actions have been more thoroughly explained, however, and now specify that corrective actions shall include ''procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including

appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein.''

This final rule also adopts the provision in the proposal requiring establishments to keep daily records documenting that sanitation and monitoring procedures listed in the Sanitation SOP's are performed. Establishments also must maintain records documenting any corrective actions taken to prevent direct contamination or adulteration of products, or when the establishment determines or FSIS notifies the establishment that its Sanitation SOP's are inadequate. FSIS has clarified that such records must be initialed and dated by the designated establishment employee(s) responsible for the implementation and monitoring of the Sanitation SOP's procedures.

In response to comments, FSIS has revised the recordkeeping requirements to allow for computer maintenance of records, as long as establishments implement controls to ensure the integrity of the electronic data. FSIS recognizes that many establishments currently use computers for maintaining a variety of types of information, including sanitation data. It would be impractical and burdensome to prohibit these establishments, or others wishing to use computers, from using computers to record and store required sanitation data.

FSIS proposed that establishments must maintain sanitation records for a minimum of six months, but did not specify whether these records had to be stored on-site. Several commenters expressed concern about the physical location of establishment sanitation records and questioned whether sanitation records must be maintained in the establishment.

FSIS requires unimpeded access to all establishment sanitation records for oversight and enforcement purposes; these records are to be an integral part of the Agency's inspection activities. FSIS anticipates that, for most establishments, these records will not be voluminous and will not create a significant storage problem. However, the Agency recognizes that space may be limited at certain inspected facilities and has revised this requirement to allow establishments to retain records off-site, provided they are not removed from the establishment for at least 48 hours following completion and they can be provided to FSIS personnel within 24 hours of being requested.

In this final rule, FSIS is clarifying that it will verify that the Sanitation SOP's are being implemented and maintained, and that they are effective. FSIS inspectors will ensure not only that an establishment is complying with the requirement to develop, implement, and maintain Sanitation SOP's, and to maintain daily records for them, but also that the Sanitation SOP's are in fact working. Inspectors will review the Sanitation SOP's, the daily records, the conduct of procedures specified in the Sanitation SOP's, and the sanitary conditions themselves.

The failure by an establishment to comply with the Sanitation SOP's regulations may initiate regulatory action. The full array of compliance tools includes process deficiency reports, tagging of equipment or areas, retention of product, letters of warning, and suspension and withdrawal of inspection. The nature of FSIS's response will depend on the circumstances. Minor omissions or errors in Sanitation SOP's documentation, not symptomatic of larger ''system'' problems, will result in regulatory action commensurate with the severity of the violation. For example, process deficiency reports might be issued to direct corrective action. However, a pattern of violations of the Sanitation SOP's provisions would lead to additional responses, with persistent and serious failures resulting in suspension or withdrawal of inspection from the establishment. Suspensions and withdrawals would be made in accordance with applicable rules of practice for those proceedings.

If FSIS determines that an establishment's Sanitation SOP's fail to include procedures to prevent direct product contamination or adulteration or that required records are not being kept, the Agency may tag affected facilities and equipment and suspend inspection until the failure is remedied. Because the tagging of insanitary facilities and equipment is based on current statutory authority, the specific regulatory provisions for tagging in the proposal are not retained in this final rule.

Verification and compliance activities under the Sanitation SOP's provisions are distinguishable from actions taken as a consequence of a finding of product adulteration under the sanitation requirements elsewhere in the regulations. As a practical matter, however, such findings are likely to be connected. A finding of deficient Sanitation SOP's or Sanitation SOP's records may prompt additional inspection activity directed at determining whether or not product contamination or adulteration has occurred. If it has, FSIS will take appropriate action to prevent adulterated product from entering commerce and, where necessary, seek recall of product that has already entered commerce.

Finally, the Sanitation SOP's requirements of this final rule are set out in a new Part 416, Sanitation. These provisions are formatted differently from the proposal to comport with FSIS's announced project to reform, reorganize, and recodify the meat and poultry regulations. This regulatory reform project is well underway, and will, among other things, eliminate unneeded regulations by combining, to the extent possible, the currently separate meat and poultry regulations. New Part 416, like new part 417 on HACCP, covers both meat and poultry products. Part 416 will be expanded and supplemented as the Agency proceeds with its initiative to review, reform, and reorganize existing FSIS regulations concerning sanitation.

Comments and Responses

General

Support for the proposed requirements for Sanitation SOP's was expressed by a wide range of commenters. Most supporters agreed that establishment sanitation is essential to product safety and that every meat and poultry establishment should be required to have a written sanitation plan. Those who opposed mandatory Sanitation SOP's argued that current sanitation regulations would be adequate if they were better enforced, that Sanitation SOP's would be no more than a paperwork exercise, and that they would be an additional burden on establishments. FSIS strongly disagrees with the notion that Sanitation SOP's will be a mere ''paperwork exercise,'' and believes this regulation will, in fact, result in improved sanitation and provide for more effective enforcement of the sanitation requirements.

Substantial evidence exists that insanitary facilities or equipment, poor food handling, improper personal hygiene, and similar insanitary conditions create an environment in which products become contaminated with microorganisms, including pathogens. While sanitation has improved greatly throughout the industry over the years, some individual establishments still have difficulty getting their facilities and equipment ready to start operations each day and keeping conditions sanitary during establishment operations. FSIS affirms that proper sanitation is an important and integral part of every food process and a fundamental requirement of the inspection laws that the Agency enforces.

In the past, FSIS has enforced the sanitation requirements primarily through a combination of prescriptive sanitation regulations, detailed guidance materials, and direct, hands-on involvement by inspectors in day-to-day pre-operational and operational sanitation procedures in inspected establishments. This system achieved sanitation goals on a daily basis in individual establishments, but at a relatively large public cost because it encouraged establishments to shift accountability for sanitation to the FSIS inspector. For example, in the past, FSIS inspectors have taken responsibility for checking sanitation in every slaughter establishment before it begins daily processing. In extreme cases, inspectors have led daily ''bucket brigades'' of slaughter establishment employees through pre-operational establishment cleanup. In these circumstances, FSIS has, in effect, taken responsibility for establishment sanitation conditions. The Sanitation SOP's requirement is intended to end this practice. Sanitation SOP's make it clear that responsibility for identifying and conducting procedures needed to maintain sanitary conditions rests with the establishment, not with FSIS.

Sanitation SOP's are an inspection tool. They will help individual inspectors focus their oversight in an establishment on those conditions that pose a risk of direct product contamination or adulteration, that is, on conditions which pose the greatest adulteration hazards to products subject to inspection in that establishment. The effectiveness of each establishment's Sanitation SOP's in achieving acceptable sanitation will be subject to continuing verification by FSIS inspectors through direct observation of conditions in the establishment. It is expected that, over time, inspectors in most establishments will increasingly be able to rely on a review of daily Sanitation SOP's records to determine whether establishments are complying with sanitation requirements. However, FSIS inspectors will continue to have a full array of regulatory tools to ensure the maintenance of sanitary conditions. For instance, FSIS inspectors will continue tagging equipment, utensils, rooms, or compartments in instances where there is physical evidence of insanitary conditions in the production areas of the establishment.

FSIS anticipates that the development, implementation, and maintenance of Sanitation SOP's, as well as the recordkeeping provisions, will impose a minimal burden on establishments. Some establishments already utilize written Sanitation SOP's. For other establishments, compliance with the Sanitation SOP's requirements will consist of recording their current sanitation practices. A complete discussion of the anticipated costs of implementing the SOP's requirements is contained in the Final Regulatory Impact Analysis.

Sanitation SOP's are an integral part of the Agency's strategy for making inspection more effective and more risk-based in its focus. For these reasons, FSIS is adopting the proposed requirements for Sanitation SOP's and is clarifying that developing, implementing, and maintaining Sanitation SOP's and keeping daily Sanitation SOP's records, is a condition of inspection.

Development of Sanitation SOP's

As noted previously, a number of commenters raised concerns about the content of the Sanitation SOP's and asked for more specificity. Some commenters recommended that FSIS be more specific about what procedures must be in the Sanitation SOP's. Other commenters suggested that such procedures be fully described and be made mandatory. The Agency recognizes these commenters' concerns and therefore is providing guidance on how individual establishments may develop their Sanitation SOP's in Appendix A and Appendix B to this final rule. Appendix A is a guideline on Sanitation SOP's that establishments can use in developing their own Sanitation SOP's; Appendix B is a model of an establishment's Sanitation SOP's that demonstrates what a completed Sanitation SOP's might include. Together, these guidance documents will assist establishments to develop Sanitation SOP's that address conditions unique to individual establishments and processes and that prevent direct product contamination or adulteration. As with all FSIS guidance materials, the Agency welcomes comments on how these two documents might be improved.

However, the final rule itself remains nonprescriptive in that it requires each establishment to determine for itself what procedures are necessary to prevent insanitary conditions that will cause direct product contamination or adulteration. Overall, the comments confirmed that, while proper sanitation is a common need in every food production facility, the means to achieve it are diverse and establishment-specific. Establishments that now have good sanitation and effective process controls are expected to continue using techniques that work in their establishment. Other establishments will need to analyze and select effective abatement procedures among various alternatives for attaining a sanitary processing environment. What works in one establishment may or may not work in another.

The proposed rule also solicited comments as to whether FSIS should mandate Good Manufacturing Practices (GMP's) for all or certain Sanitation SOP's. FSIS listed illustrations in the proposal of elements that might be mandatory elements of Sanitation SOP's. Although some commenters expressed support for making GMP's or other practices mandatory, many objected to such specific requirements on the basis that they would be infeasible. FSIS agrees with those commenters who stated that detailed GMP regulations are infeasible because of the difficulty in making them specific enough to be useful. FSIS also was concerned that such specificity could result in lost flexibility.

For these reasons, this final rule will not prescribe a single format for individual establishment Sanitation SOP's or mandate specific GMP's. It will be the responsibility of each establishment to consider existing FSIS regulations and guidelines; evaluate its facilities, processes, and sanitation conditions; determine what sanitation procedures must be implemented to prevent direct product contamination or adulteration; and describe these procedures in Sanitation SOP's.

Maintaining Sanitation SOP's

FSIS received several comments regarding the maintenance of Sanitation SOP's. Some commenters wanted to know whether if an establishment will be able to update its Sanitation SOP's to incorporate new technologies. Other commenters wanted to know what type of system, if any, FSIS will use to review changes to Sanitation SOP's and if a formal request for FSIS review or approval would be required.

As has been discussed previously, the final rule requires that each establishment develop, implement, and maintain its Sanitation SOP's and incorporate new sanitation technologies as appropriate. FSIS encourages the adoption of new technologies that can improve sanitation and food safety. This is an establishment responsibility. Although FSIS will not approve Sanitation SOP's, it will provide advice and guidance to establishments as they develop and begin to implement Sanitation SOP's.

Recordkeeping

Commenters also expressed concerns about what was to be in daily sanitation

records and how long and where such records were to be retained. As the proposal explained, and this final rule requires, Sanitation SOP's records must document the implementation and maintenance of Sanitation SOP's, as well as any deviations from Sanitation SOP's procedures, and corrective actions taken. As with the development of Sanitation SOP's themselves, FSIS will allow each establishment to determine the form and format of its daily sanitation records. In many establishments, a simple, daily checklist, showing that specific Sanitation SOP's procedures were implemented, initialed by the responsible establishment employee, is likely to suffice. Other establishments may find a more detailed format for its records is more useful. Some establishments may wish to use a computer-based system. This final rule provides such flexibility.

Some commenters stated that the proposed six-month retention of daily sanitation records was too long. FSIS disagrees and is adopting the proposed requirement that establishments retain Sanitation SOP's records for six months. Increased product shelf-life and the potential need for FSIS personnel to review Sanitation SOP's records many months after production make it necessary that establishments retain records for six months. Furthermore, sanitation records provide both FSIS and establishment management near-term trend data to evaluate how establishment sanitation is being carried out under the Sanitation SOP's. This feedback should be very useful to establishments in determining whether and how their Sanitation SOP's need revision. Inspectors will benefit, too, from knowing how the establishment has complied with these requirements. Establishment sanitation records will also need to be reviewed by the Agency as part of any compliance investigation.

In a related matter, several commenters expressed concern about the physical location of establishment sanitation records and questioned whether sanitation records must be maintained in the establishment. As explained above, FSIS requires unimpeded access to all establishment sanitation records for oversight and enforcement purposes. FSIS anticipates that, for most establishments, these records will not be voluminous and will not create a significant storage problem. However, in response to these comments, this final rule will allow establishments to retain Sanitation SOP's records off-site provided they are not removed from the establishment for at least 48 hours following completion and they can be provided to FSIS personnel within 24 hours of request.

Some commenters also expressed concern about public accessibility to an establishment's Sanitation SOP's records. Like establishment HACCP records, these records are kept and maintained by the establishment and generally are not Agency records. Occasionally, however, such records will be copied and incorporated into Agency records for some official purpose. These records will be disclosed to third parties only to the extent disclosure is required by the Freedom of Information Act and the Privacy Act or other applicable law. Proprietary information, personal information, and other information exempt from disclosure would be protected.

''Layering''

Many commenters were concerned that FSIS was layering requirements for Sanitation SOP's over existing regulations governing establishment sanitation practices, thereby increasing rather than decreasing intrusive, command-and-control oversight of all inspected establishments. Concern was also expressed that the new requirements might conflict with current sanitation regulations.

FSIS does not consider the Sanitation SOP's requirement to be layered over or in conflict with existing regulations. Existing regulations establish substantive sanitation-related requirements, while the new Sanitation SOP's provisions establish a means by which establishments will take responsibility for achieving sanitary conditions and preventing direct product contamination or adulteration. Sanitation SOP's also will better focus inspection oversight by FSIS inspectors on those sanitation measures required to prevent direct product contamination or adulteration. As discussed, one of the Agency's goals is to reduce inspectors' personal involvement in the conduct of routine, day-to-day sanitation procedures.

FSIS emphasizes that it does not intend or require that an establishment's Sanitation SOP's incorporate all elements of the existing FSIS sanitation regulations. These regulations contain many detailed provisions that do not relate to the prevention of direct product contamination. As the text of the Sanitation SOP's regulations and the guidance materials at Appendices A and B makes clear, FSIS intends and requires only that the Sanitation SOP contain a description of the procedures an establishment will follow to address the elements of pre-operational and operational sanitation that relate to the prevention of direct product contamination.

For example, under paragraph (a) of § 308.4 of the regulations, FSIS requires that ''Dressing rooms, toilet rooms, and urinals shall be sufficient in number, ample in size, and conveniently located.'' Although compliance with this requirement is important for the maintenance of establishment sanitation, and employee hygiene must be part of Sanitation SOP's, § 308.4(a) does not concern direct product contamination and would not need to be addressed in an establishment's Sanitation SOP's. On the other hand, the rule requires that Sanitation SOP's specifically address the pre-operational ''cleaning of food contact surfaces of facilities, equipment, and utensils'' because these procedures are necessary to prevent the direct contamination of product. Additionally, the guidance materials in Appendices A and B give examples of other procedures necessary to prevent direct product contamination that Sanitation SOP's should include, such as ''Descriptions of equipment disassembly, reassembly after cleaning, use of acceptable chemicals according to label directions, and cleaning techniques.'' FSIS emphasizes, however, that an establishment does not need to reproduce in its written Sanitation SOP's the existing regulatory requirements concerning the prevention of direct contamination or adulteration of product.

FSIS also realizes that its existing sanitation regulations contain some detailed and prescriptive provisions and that some of those regulations may be outmoded and no longer needed in light of the Agency's effort to clarify that good sanitation is the responsibility of each establishment. FSIS will continue to review, reevaluate, and revise, as necessary, all current sanitation regulations, along with related issuances and sanitation inspection procedures, to simplify and streamline them and make them more compatible with Sanitation SOP's requirements. This process was announced and initiated in the advance notice of proposed rulemaking published on December 29, 1995 (60 FR 67469). The review of sanitation regulations is a high priority for the Agency. The elements of sanitation that are required to be addressed in the Sanitation SOP's will remain as central elements of the FSIS sanitation regulations. Establishments will not need to revise their Sanitation SOP's because of the simplification and streamlining of existing FSIS sanitation regulations.

Role of Inspectors

A related concern of many commenters was the role FSIS inspectors will play in the development and enforcement of Sanitation SOP's. Some commenters expressed concern that during inspection inspectors would rely solely on record reviews instead of actually observing establishment conditions. Other commenters expressed concerns that Sanitation SOP's would merely provide FSIS inspectors with more latitude to make intrusive and arbitrary decisions.

FSIS strongly disagrees with this characterization of Sanitation SOP's and the role of the Agency's inspection personnel. Industry's responsibility for producing safe meat and poultry and FSIS's responsibility for regulatory oversight are fundamentally different. Sanitation SOP's are the establishment's commitment to FSIS that they will consistently provide a sanitary environment for food production. FSIS inspectors will not be tasked with directing an establishment's sanitation procedures, nor with ''approving'' the establishment's Sanitation SOP's. They will, however, verify that the Sanitation SOP's are being implemented and that they are effective in preventing direct product contamination and adulteration.

Oversight of Sanitation SOP's will become an increasingly important part of daily inspection activity, while the directing of sanitation activities will occur less frequently. Periodic inspection tasks will include verifying that Sanitation SOP's meet the regulation's requirements, are being implemented and maintained, and are effective in producing sanitary conditions. FSIS inspectors' oversight will include review of the Sanitation SOP's and required records, direct observation of the implementation and monitoring of the Sanitation SOP's, and visual observation of sanitary conditions in the production areas of the establishment.

FSIS expects that establishments will rely less on inspectors to direct them in maintaining sanitary conditions as establishments rely more on adherence to their own Sanitation SOP's. The mix of inspector tasks that comprise sanitation inspection also will change. As establishments adopt and successfully implement Sanitation SOP's, and consistently achieve good sanitation results, FSIS inspectors can spend less time ensuring that basic sanitation requirements are being met. Conversely, to the extent some establishments do not implement effective Sanitation SOP's and consistently achieve good sanitation, FSIS inspectors will be obliged to intensify their focus on actual establishment conditions and initiate appropriate enforcement actions.

Ensuring establishments operate under sanitary conditions should be made easier for inspectors, and ultimately permit inspectors to spend more time on other tasks. One purpose of the Sanitation SOP's regulations is to help inspectors, as well as establishments, focus their attention on those aspects of establishment sanitation that pose the most risk of causing product contamination or adulteration. Under the current inspection system, inspectors look at all aspects of establishment sanitation, including many that have a relatively low probability of causing product contamination. In the future, normal oversight activities will focus more on whether an establishment is following its Sanitation SOP's and thereby consistently preventing, or as appropriate, correcting, conditions that cause direct product contamination or adulteration. Some commenters were concerned about the effect on establishment operations if inspection personnel, when enforcing the Sanitation SOP's requirements, reject one piece of equipment, utensil, room or compartment as insanitary. As previously stated, inspectors will take prompt action in cases where there is a finding of insanitation or the likelihood of product contamination or adulteration. The type and intensity of this response will vary. For example, establishment operations may be allowed to continue if inspection personnel determine that a rejected item, compartment or room is not related to other processes or products being produced. However, inspection would be withheld in rooms, departments, or facilities associated with the production of contaminated or adulterated products where the establishment can not show FSIS that they have isolated the cause of the contamination or adulteration and have taken appropriate action to prevent further contamination or adulteration. In a similar vein, commenters also stated that establishments should not be penalized for the occurrence of a sanitation problem that is effectively abated. These commenters suggested that ''U.S. Rejected'' tags should be used only if an establishment fails to identify and correct insanitary conditions. If the establishment takes proper corrective action, they argued, it should be viewed as evidence that the Sanitation SOP's is being adequately implemented. FSIS agrees. Establishments that identify and correct insanitary conditions in a timely manner and make proper disposition of any affected product will be considered to be in compliance with the Sanitation SOP's regulations.

Although FSIS fully expects that the clarification of establishments' sanitation responsibilities will lead to better and more consistent compliance with sanitation requirements, the Agency recognizes that this will not be the case in all establishments. Establishments that fail to comply with the requirements in this final rule for Sanitation SOP's will be subject to appropriate compliance and regulatory action that will, when necessary, include suspension or withdrawal of inspection. Further, as noted in the proposal, anyone who intentionally falsifies records will be subject to criminal prosecution.

FSIS also recognizes commenters' concerns about its rules of practice and due process procedures. FSIS expects that these concerns will be addressed through changes to these procedural requirements initiated as a result of the Agency's regulatory reform project. These subjects are also on the agenda for discussion at FSIS's upcoming implementation conferences.

Relation to HACCP

Another important topic raised by commenters was the link between an establishment's Sanitation SOP's and its HACCP plan. This link was unclear to some who stated the two were redundant. HACCP plans aim at ensuring safety at specific critical control points within specific processes, while Sanitation SOP's typically transcend specific processes. Sanitation SOP's are important tools for meeting existing statutory sanitation responsibilities and preventing direct product contamination or adulteration. As such, it is appropriate that they be developed and implemented in the near-term prior to implementation of HACCP. In a sense, the Sanitation SOP's are a prerequisite for HACCP. It is anticipated that some procedures addressed in an establishment's Sanitation SOP's might eventually be incorporated into an establishment's HACCP plan. Other procedures in an establishment's Sanitation SOP's, including those addressing pre-operational sanitation procedures for cleaning facilities, equipment, and utensils, will most likely remain in the Sanitation SOP's. A sanitation procedure that is incorporated into a validated HACCP plan need not be duplicated in the Sanitation SOP's.

Training

A number of comments expressed concern about the content of inspector training, suggesting that inadequate training would result in inconsistent enforcement of the rule. Assurance was requested that inspectors would be trained to consistently monitor Sanitation SOP's. FSIS recognizes that inspectors must be trained to react as regulators rather than as quality control consultants or establishment sanitarians when a sanitation or other health and safety problem is discovered in an establishment. A primary focus of agency training sessions will be to attain this goal.

Also, some commenters asked whether joint FSIS and industry training would be offered. FSIS does not plan to allow industry to attend Agency training sessions. However, FSIS does plan to hold informational briefings for industry personnel. These will be the subject of future notices in the Federal Register.

Pre-Operation Sanitation Inspection

Some commenters asserted that establishments with good Sanitation SOP's should be permitted to start daily operations on their own, instead of having to wait for an inspector to conduct a pre-operational sanitation inspection and allow operations to start. FSIS agrees with these commenters. Accordingly, upon the effective date of this rule and implementation of Sanitation SOP's, establishments not otherwise notified by FSIS may begin daily processing upon completion of pre-operational sanitation activities without the prior approval of an inspector.

Extending the implementation date for Sanitation SOP's will also give FSIS additional time to provide needed training, instruction and management support to FSIS inspection personnel tasked with enforcing the Sanitation SOP's requirements.

Implementation Date

Finally, many commenters expressed concern about the amount of time they said it would take to prepare and implement effective Sanitation SOP's. These commenters requested more lead time to implement these requirements. FSIS agrees that some establishments may need more time than the 90 days the proposed rule provided for implementing Sanitation SOP's requirements. Consequently, FSIS is modifying this aspect of the proposal. This final rule will provide establishments six months from the effective date of this regulation to develop and implement written Sanitation SOP's. This additional time will allow these establishments to initially develop and refine their Sanitation SOP's to best meet operational needs before the effective date of the Sanitation SOP's requirements. Extending the implementation date for Sanitation SOP's will also give FSIS additional time to provide needed training, instruction, and management support to personnel tasked with enforcing the Sanitation requirements.

IV. Microbiological Performance Criteria and Standards

Summary of Proposal

As part of the Pathogen Reduction/HACCP proposal, FSIS proposed interim targets for the reduction of *Salmonella* for the major species and for ground meat and poultry. Further, FSIS proposed to require daily testing by slaughter establishments and establishments producing raw ground product in order to verify achievement of the *Salmonella* targets on an ongoing basis. The proposal reflected a central tenet of the FSIS food safety strategy: to be effective in improving food safety and reducing the risk of foodborne illness, HACCP-based process control must be combined with objective means of verifying that meat and poultry establishments are achieving acceptable levels of food safety performance.

FSIS explained in the preamble to the proposal that food safety performance standards, in the form of tolerances or other limits, have been an important feature of the food safety regulatory system for chemical residues (such as those resulting from the use of animal drugs and pesticides) and for pathogenic microorganisms in ready-to-eat meat and poultry products (such as *Listeria monocytogenes* in ready-to-eat products and *Salmonella* in cooked beef). However, performance standards have not in the past been incorporated into the regulatory system for pathogens on raw meat and poultry products.

FSIS recognizes that establishing performance standards for pathogens on raw products raises different and difficult issues. The microbiological safety of a meat or poultry product at the point of final sale or consumption is affected by many factors. Most significantly, unlike other kinds of contaminants, microbiological pathogens can be introduced at many points on the farm-to-table continuum, and once in the product, under certain conditions, the bacteria can multiply. Some pathogens, such as *E. coli* O157:H7, are so virulent that a small number of organisms can pose a significant hazard. Indeed, on that basis the Agency has determined that any amount of *E. coli* O157:H7 will adulterate a meat or poultry product. On the other hand, some pathogens, such as *Salmonella*, ordinarily must multiply to relatively large numbers to cause illness, although the susceptibility of individuals to illness varies widely. Certain segments of the population, such as the very young, the elderly, and persons with compromised immune systems, are particularly vulnerable to illnesses caused by *Salmonella* and other foodborne pathogens.

Therefore, FSIS has not taken the position in this rulemaking that some amount of a pathogen necessarily renders a raw meat or poultry product unsafe and legally adulterated; the proposed targets for pathogen reduction would not have served as a standard for determining whether any particular lot of raw product could be released into commerce. The proposed targets were intended instead as an initial step toward defining levels of food safety performance that establishments would be required to achieve consistently over time. The interim targets and the required testing by establishments were also intended as a first step toward the eventual incorporation of microbial testing as an integral part of process-control validation and verification in facilities operating under HACCP.

Salmonella was selected as the target organism because it is the most common cause of foodborne illness associated with meat and poultry products. It is present to varying degrees in all major species. And, interventions targeted at reducing *Salmonella* may be beneficial in reducing contamination by other enteric pathogens.

As interim targets for pathogen reduction, FSIS proposed that the prevalence of *Salmonella* contamination in each of the major species and in raw ground products be reduced by each establishment to a level below the current national baseline prevalence as measured by the FSIS Nationwide Microbiological Baseline Data Collection Programs and Nationwide Microbiological surveys (collectively referred to below as the FSIS baseline surveys) or other available data.

Role of Microbiological Performance Criteria and Standards in FSIS Food Safety Strategy

As explained in the ''*Background*'' section of this preamble, the most important objective of this rulemaking is to build into food production processes and the FSIS system of regulation and oversight, effective measures to reduce and control pathogenic microorganisms

on raw meat and poultry products. FSIS has concluded that HACCP-based process control combined with appropriate microbiological performance criteria and standards will achieve this objective.

Because the current regulatory system lacks any performance criteria or standards for harmful bacteria on raw products (other than with respect to *E. coli* O157:H7 on raw ground beef), FSIS inspectors have no adequate basis for judging whether establishments producing raw meat and poultry products are dealing effectively with the food safety hazard posed by harmful bacteria.

The HACCP requirements discussed in the preceding section of this preamble will ensure that all meat and poultry establishments implement science-based process controls designed to prevent and reduce the significant food safety hazards that arise in their particular production processes and products. For slaughter establishments and other establishments producing raw meat and poultry products, this will mean developing controls that address the hazards posed by pathogenic microorganisms as well as other biological, chemical and physical hazards. HACCP principles provide the framework by which establishments target and reduce harmful bacteria on raw meat and poultry products.

To be successful in ensuring food safety, however, HACCP must be coupled with appropriate performance criteria and standards against which the effectiveness of the controls developed by each establishment can be validated and verified. For example, controls designed to prevent the contamination of processed, ready-to-eat meat and poultry products with harmful bacteria would have to be validated as effective in meeting the already-existing requirement that such products be free of harmful bacteria. Without such performance criteria and standards, there would be no objective basis for determining whether a particular HACCP plan is adequate for its food safety purpose. Additionally, there would be no way to determine whether industry or FSIS had met their respective food safety responsibilities.

In this rulemaking, FSIS for the first time proposed microbiological performance standards for raw products. The need for some measure of performance in the area of microbiological contamination was generally supported by the comments FSIS received on its proposal. In response to the comments, FSIS has refined and improved its proposed approach, and is establishing microbiological performance standards for reduction of *Salmonella* in raw products, coupled with performance criteria for use with *E. coli* testing to verify the effectiveness of process controls in slaughter establishments.

These new provisions are the first steps in what FSIS expects to be a long-term effort to ensure that appropriate microbial testing is conducted, and appropriate criteria and standards exist, to reduce the food safety hazards posed by harmful bacteria on raw meat and poultry products. The numerical targets for both the performance criteria and the pathogen reduction performance standards are likely to be changed as new data become available. The targets currently are set at the national baseline prevalence of contamination and reflect what is achievable using available technology. FSIS intends to repeat periodically its baseline surveys, on which the criteria and standards are based. FSIS will collect additional data on *Salmonella* by testing products in establishments pursuant to the performance standards and on *E. coli* through close monitoring of establishments' experience and test results associated with that mode of process control verification. These new data, together with relevant epidemiologic data, scientific research, and new technologies, will be considered by FSIS when proposing future revisions to the performance criteria and testing requirements for *E. coli* and the pathogen reduction performance standards for *Salmonella*. New information and data also may support different standards and different approaches to microbial testing.

FSIS is committed to the development and implementation of future performance standards, as needed, to achieve the FSIS's public health goal of reducing the incidence of foodborne illness associated with harmful bacteria on raw meat and poultry products. FSIS is also concerned that standards achieve this public health goal in a manner that encourages industry innovation and minimizes regulatory burdens on the regulated industry. The pathogen reduction performance standards promulgated in this regulation will be implemented on the basis of a statistical evaluation of the prevalence of bacteria in each establishment's products, measured against the nationwide prevalence of the bacteria in the same products. These standards will not be used to judge whether specific lots of product are adulterated under the law. As more research is done and more data become available, and as more sophisticated techniques are developed for quantitative risk assessment for microbiological agents, it may be possible and appropriate to develop performance standards that use a different approach. Consideration may also be given to the possibility of establishing similar standards for other pathogenic microorganisms. FSIS will continue to work with the scientific community in this area.

The microbiological performance standards set out in this rulemaking are part of a fundamental shift in FSIS regulatory philosophy and strategy. The current inspection system relies heavily on intensive ''command-and-control'' prescription of the means by which meat and poultry establishments must achieve statutory objectives concerning food safety, sanitation, product wholesomeness, and prevention of economic adulteration and misbranding. As explained in the ''*Background*'' section of this preamble, in FSIS's ANPR ''FSIS Agenda for Change: Regulatory Review,'' and in the January, 1996, National Performance Review report ''Reinvention of Food Regulations,'' FSIS plans to shift from this reliance on command and control regulations to much greater reliance on performance standards. FSIS believes that public health and consumer protection goals can be achieved more effectively, in most cases, by converting command-and-control regulations to performance standards, which provide industry with the flexibility to devise the optimal means of achieving food safety objectives. FSIS would verify compliance with such performance standards through inspection and other forms of oversight.

Overview of Final Rule

Comments on the proposed rule's microbial testing provisions have resulted in a number of changes to those provisions. As discussed in the ''Response to Comments'' section, below, FSIS received numerous comments supporting the concept of microbiological performance criteria or standards, but also received many comments urging alternatives to the specific approach proposed by FSIS, including testing for organisms other than *Salmonella*.

The Agency actively sought out comment and information on the issue of target organism(s) to be selected for process control verification and pathogen reduction purposes in this regulation. In the proposal, FSIS stated that ''the Agency recognizes that there are other foodborne human pathogens of public health concern that can be isolated from raw meat and poultry product. The Agency would welcome

comments on the targeting of other pathogens in addition to or in lieu of *Salmonella*'' (60 FR 6800). As noted earlier in this preamble, during the comment period FSIS held many meetings to solicit comment on various issues, including microbiological criteria and standards. Microbiological criteria and standards were discussed in detail at the FSIS-sponsored scientific conference held in Philadelphia, Pennsylvania, on May 1 and 2, 1995, titled ''The Role of Microbiological Testing in Verifying Food Safety.'' This conference was open to the public and was announced in the Federal Register on March 24, 1995 (60 FR 15533). An expert panel at that conference endorsed the role of microbiological testing in accordance with appropriate criteria or standards, but suggested that mandatory establishment testing focus on a quantitative assay for generic *E. coli* rather than the proposed qualitative assay for *Salmonella*. The panel stated that a quantitative assay for the more commonly occurring generic *E. coli* is a more effective process control indicator with respect to the prevention of contamination of meat and poultry by feces and associated bacteria.

FSIS also held a series of six issue-focused public meetings in September, 1995. During a preliminary public meeting on August 23, 1995, at which issues were identified and the meeting agenda was established, participants decided that a full day should be devoted to further public discussion of pathogen reduction standards and microbial testing. The agenda for the six meetings appeared in the Federal Register on August 31, 1995 (60 FR 45381). The issues discussed on September 27 included: (1) the scientific and policy basis for establishing targets; (2) whether *Salmonella* is the appropriate organism for some or all species; (3) whether other pathogens would be preferable for some or all animal species; (4) the utility of targets for *E. coli* or other non-pathogenic indicator organisms as a means of controlling and reducing pathogenic microorganisms; (5) the advantages and disadvantages of targets based on the prevalence of detectable contamination vs. targets based on the number of organisms present; and (6) the need for pathogen reduction targets for raw ground products in general and in establishments that both slaughter animals and produce ground product.

At the September 27, 1995, issue-focused meeting, there was additional comment in favor of testing for an organism other than *Salmonella*, such as generic *E. coli*, that has a strong track record in the industry as a good organism to use for process control verification testing. There was, however, continued strong support for raw product testing targeted at pathogens, such as *Salmonella*, and support for pathogen reduction as the primary goal of such testing.

At the meetings, FSIS distributed issue papers on the various issues being addressed, based in large part on comments already received. The issue paper on Pathogen Reduction Performance Standards and Microbial Testing stated that the two most common concerns in the comments received to that date were the proposed selection of *Salmonella* as the indicator organism and the frequency of proposed testing. It stated that although some commenters recommended finalizing *Salmonella* testing, others recommended using *E. coli* instead of or in addition to *Salmonella*. The issue paper stated the Agency's current thinking on the organism to be selected, the need for daily testing at every establishment, and the necessity of testing each species slaughtered and each ground product produced. In the issue paper FSIS stated, among other things, that it was ''seriously considering generic *E. coli* as the process control indicator organism and the adoption of a quantitative *E. coli* standard as a measure of process control with respect to the prevention and reduction of fecal contamination in slaughter plants.'' FSIS also stated that it was considering setting forth pathogen-specific performance standards as a direct measure of accountability for controlling and reducing harmful bacteria in raw meat and poultry products and that *Salmonella* targets might be adopted as performance standards and enforced by FSIS through its own compliance monitoring. The Agency published the issue papers in the Federal Register on October 24, 1995 (60 FR 54450).

Based on the large body of written and oral comments FSIS has received on this issue, the Agency has decided not to use *Salmonella* both as a target for pathogen reduction and as an indicator of process control. FSIS has decided to adopt pathogen reduction performance standards targeting *Salmonella*, as proposed, except that FSIS, not the establishments, will conduct testing for the pathogen to verify compliance. FSIS also has decided to require establishments slaughtering livestock and poultry to conduct routine testing for generic *E. coli* (instead of the proposed use of *Salmonella* tests) as an ongoing, objective process control indicator for fecal contamination, and to establish performance criteria by which results can be evaluated.

Process Control Verification Performance Criteria

Under the FMIA and the PPIA, meat and poultry establishments inspected by FSIS are required to maintain sanitary conditions sufficient to prevent contamination of products with filth and to prevent meat and poultry products from being rendered injurious to health (21 U.S.C. 601(m) and 608 (FMIA); 21 U.S.C. 453 (g) and 456 (PPIA)). A grant of inspection by FSIS is contingent upon an establishment meeting this responsibility. FSIS is authorized by law to issue regulations establishing appropriate sanitation requirements. Meat and poultry products are deemed legally adulterated, whether or not they are shown to be contaminated, if prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material and ingesta, both within the gastrointestinal tract and on the exterior surfaces of animals going to slaughter. Therefore, without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Additionally, once introduced into the establishment environment, the organisms may be spread from carcass to carcass.

Because the microbial pathogens associated with fecal contamination are the single most likely source of potential food safety hazard in slaughter establishments, preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments. Further, because such contamination is largely preventable, controls to address it will be a critical part of any slaughter establishment's HACCP plan. Most slaughter establishments already have in place procedures designed to prevent and remove visible fecal contamination.

There is general agreement within the scientific community that generic *E. coli* is the best single microbial indicator for fecal contamination. FSIS, therefore, is requiring that establishments slaughtering livestock or poultry begin testing for *E. coli* (*E. coli*, biotype I, nonspecific as to species, hereinafter referred to simply as *E. coli*) at the

frequency and following the procedures described in ''*Process Control Verification; E. coli Performance Criteria and Testing*'' section, below, 6 months after publication of the final rule. FSIS considers the required testing to be essential for meeting current statutory requirements for sanitation and the prevention of adulteration. This testing also will play an integral role in the successful implementation of HACCP in slaughter establishments. In addition, FSIS is establishing process control performance criteria for fecal contamination based on the frequency and levels of contamination of carcasses with *E. coli.*

As explained below, FSIS is establishing performance criteria to reflect the prevalence and levels of contamination of *E. coli* on carcasses produced nationwide, as determined by FSIS baseline surveys. The performance criteria and required testing will provide each slaughter establishment and FSIS with an objective means of verifying that the establishment is achieving this level of performance and maintaining it consistently over time. Test results that show an establishment is meeting or exceeding the criteria provide evidence that the establishment is maintaining adequate process control for fecal contamination.

FSIS is purposely using the term performance ''criteria'' rather than performance ''standard'' in this context because no single set of test results can demonstrate conclusively that adequate process control for fecal contamination is or is not being maintained. As explained below, if test results do not meet the applicable criterion, it raises questions about the adequacy of the process control. FSIS intends to consider the establishment's results and corrective actions, together with other information and inspectional observations, in evaluating whether a problem exists that requires regulatory action or other measures to protect consumers and ensure compliance with the law.

Also, as discussed below, although FSIS is proceeding with the final rule at this time, it is inviting comment on technical aspects of the process control performance criteria and the required testing. FSIS requests that comments on the *E. coli* performance criteria and testing requirement be focused on the technical aspects of the rule, i.e., the manner in which the criteria are articulated, the sampling frequency, and the sampling and testing methodologies.

FSIS intends to update the criteria periodically to ensure that the criteria adequately reflect an appropriate level of performance with respect to prevention and removal of fecal contamination and associated bacteria from livestock and poultry carcasses.

Pathogen Reduction Performance Standards

As proposed, FSIS is adopting pathogen reduction performance standards using *Salmonella* as the target organism. The most significant difference between the proposal and this final rule is that, as explained above, FSIS is not relying on *Salmonella* to be a process control indicator, as well as the target organism for the pathogen reduction performance standard. Establishments will not be required by this final rule to test for *Salmonella*, as had been proposed. Instead, FSIS will obtain samples from slaughter establishments and establishments producing raw ground product or fresh pork sausage and test those samples for *Salmonella* to ensure that the pathogen reduction performance standards are being met.

As proposed, FSIS will require that no establishment can have a prevalence of *Salmonella* contamination, as a percentage of positive samples from carcasses and percentage of positive samples from raw ground product, greater than the baseline prevalence for each raw product as reflected in the FSIS baseline survey for each species or other category of raw product. These targets constitute performance ''standards'' rather than performance ''criteria'' because, following an establishment's implementation of HACCP, FSIS will require that the establishment meet the standard consistently over time as a condition of maintaining inspection.

The *Salmonella* pathogen reduction performance standards are not, however, lot release standards, and the detection of *Salmonella* in a specific lot of raw product will not by itself result in the condemnation of that lot. The performance standards and FSIS's enforcement approach, as discussed below, are intended to ensure that each establishment is consistently achieving an acceptable level of performance with regard to controlling and reducing harmful bacteria on raw meat and poultry products.

FSIS considers systematic reduction of pathogenic microorganisms in raw product to be an essential responsibility of meat and poultry establishments under the current statutes. As a condition of inspection and to avoid the production of product that would be deemed legally adulterated, establishments must utilize available process control methods and technologies as necessary to achieve applicable pathogen reduction standards.

Process Control Verification; E. coli Performance Criteria and Testing

Establishments that slaughter livestock and poultry currently have an obligation to control the slaughter and sanitary dressing process so that contamination with fecal material and other intestinal contents is prevented. This means that establishments must maintain sanitary conditions and use good manufacturing practices to avoid contamination with visible feces and ingesta and associated bacteria. When such visible contamination occurs, establishments are expected to detect it and physically remove it through knife trimming or other approved removal procedures. The present FSIS verification activity to demonstrate that this has been accomplished is organoleptic inspection. FSIS inspectors apply a zero tolerance performance standard for visible feces and ingesta on dressed carcasses. As a practical matter, however, additional measures must be taken if inspectors are to assess the extent to which the invisible bacteria associated with feces and ingesta may be present on the carcass.

FSIS has concluded, based on its proposal and the comments received, that the current practice of organoleptic examination by inspectors and the physical removal of visible contamination by establishments needs to be supplemented with an establishment-conducted microbial verification activity. This microbial testing is designed to verify, for the establishment and FSIS, that the establishment has controlled its slaughter process with respect to prevention and removal of fecal material and ingesta and associated bacteria.

Rationale for Using E. coli Tests to Verify Process Control

E. coli testing is more useful than the originally proposed *Salmonella* testing in verifying that a slaughter process is under control. This was expressed in numerous comments on the proposal, comments generated in FSIS public hearings, and the results of the scientific and technical conference on the Role of Microbiological Testing in Verifying Food Safety. The expert panel at that conference stated:

> Microbial testing is an essential element for verifying process control of raw meat and poultry. A variety of indicators exists, but the panel concluded that quantitative measurement of *Escherichia coli* would be more effective than qualitative *Salmonella* testing. When processes are under control for

E. coli, the potential presence of enteric pathogens will be minimized.[1]

The panel compared selection criteria for the choice of an indicator organism and considered alternative microbial targets such as *E. coli, Enterobacteriaceae,* and aerobic plate count, to be used alone or in combination with *Salmonella* testing. In reaching its conclusion that *E. coli* would be the most effective measure of process control for enteric pathogens, the panel considered the ideal characteristics of microbial indicators for the stated purpose. Important characteristics of *E. coli* are:

- There is a strong association of *E. coli* with the presence of enteric pathogens and, in the case of slaughtering, the presence of fecal contamination.
- *E. coli* occurs at a higher frequency than *Salmonella*, and quantitative *E. coli* testing permits more rapid and more frequent adjustment of process control.
- *E. coli* has survival and growth characteristics similar to enteric pathogens, such as *E. coli* O157:H7 and *Salmonella.*
- Analysis for *E. coli* poses fewer laboratory safety issues and testing at the establishment site is more feasible than such testing with *Salmonella.*
- There is wide acceptance in the international scientific community of its use as an indicator of the potential presence of enteric pathogens.

In the panel's view, microbial testing should be used to demonstrate process control; they concluded that a proximate indicator for enteric pathogens is needed for demonstrating process control with respect to fecal contamination. The panel concluded that *E. coli* would be the single most effective indicator for this purpose. The panel's conclusion reinforces previous statements by the NAS that ''at present, *E. coli* testing is the best indicator of fecal contamination among the commonly used fecal-indicator organisms.'' [2] FSIS agrees with these conclusions.

If future scientific research identifies another organism or group of organisms which would prove as effective in measuring process control for fecal contamination, FSIS would consider appropriate revisions to the regulations.

Use of Baseline Values to Establish E. coli Performance Criteria

The presence of some microorganisms on raw meat and poultry is unavoidable and highly variable. The goal of process control in a slaughter establishment is to minimize initial microbial contamination of the carcasses, remove harmful microorganisms that nonetheless may be present, control the proliferation of any remaining microorganisms, and prevent re-contamination. Process control criteria based on data from FSIS's nationwide baseline surveys will aid establishments in achieving this goal and complement the transition to HACCP.

FSIS collects data to develop and maintain a general, ongoing microbiological profile of carcasses for selected microorganisms of varying degrees of public health concern, and organisms or groups of organisms of value as indicators of general hygiene or process control, and to document changes in the profiles over time. FSIS's Nationwide Microbiological Baseline Data Collection Programs provide for sampling over a year's time to account for possible seasonal variations. This was the approach taken in collecting data from carcasses for all slaughter classes: steer/heifer, cow/bull, broilers, market hogs, and turkey. Sampling is designed to represent the vast majority of raw meat and poultry products produced, in most cases approximately 99% of the product produced. These programs are nationwide in scope. Enough samples are taken to enable the Agency to describe the annual distribution of test results. The number of samples collected also allows for control of sampling variation and non-sampling errors (such as missing samples, incomplete data, and inconsistent data). By contrast, FSIS's Nationwide Surveys provide a snapshot over a specified period of time less than a year. They involve a large enough number of samples to ensure a reasonable level of precision for estimates, given the prevalence of the microorganisms included in the surveys. This was the approach taken in developing baseline data for other raw meat and poultry products: ground beef (at inspected establishments and at retail), ground chicken, ground turkey, and fresh pork sausage.

For the current baselines, carcass samples were taken from fresh, whole chilled carcasses after slaughter and dressing but before any further processing took place. Samples were analyzed fresh, not frozen, to gather more accurate data on numbers of microorganisms, especially those that are more susceptible to freezing, such as *Campylobacter jejuni/coli.* FSIS personnel collected the samples tested in the surveys using standard Agency procedures for taking aseptic samples from animal tissues and for ensuring random sample selection.[3,4]

Reports of FSIS baseline programs and surveys are issued after testing results have been compiled and analyzed. Reports have been completed for cattle, broiler chickens, hogs, ground beef, ground chicken, and ground turkey. The collection and analysis of samples for the turkey baseline program and the fresh pork sausage survey will be underway soon; criteria for turkeys and fresh pork sausage will be determined upon completion of the sampling and analysis of results.

Establishment of E. coli Performance Criteria to Verify Process Control

Using data from the baseline surveys described in the preceding section, FSIS has developed animal species-specific, minimum performance benchmarks, or performance criteria, for *E. coli* on carcasses.

As explained above, these criteria are not enforceable regulatory standards. The *E. coli* performance criteria are intended to assist slaughter establishments and FSIS in ensuring that establishments are meeting their current statutory obligation to prevent and reduce contamination of carcasses by fecal material, ingesta, and associated bacteria. The criteria are flexible and are subject to amendment as FSIS and the industry gain experience with them and accumulate more data on establishment performance. The criteria are intended specifically to provide an initial basis upon which slaughter establishments and FSIS can begin to use microbial testing to evaluate the adequacy of establishment process controls to prevent feces, ingesta, and other animal-derived contaminants from contaminating the tissues intended for use as food.

FSIS has designed the criteria so that establishments meeting them are achieving results, in terms of *E. coli* levels, consistent with those being achieved by a large majority of the slaughter production in the United States, as reflected in the FSIS baseline

[1] Expert Panel's Summary Report and Recommendations, Scientific and Technical Conference on Role of Microbiological Testing in Verifying Food Safety, May 1–2, 1995.

[2] Subcommittee on Microbiological Criteria, Committee on Food Protection, Food and Nutrition Board, National Research Council. 1985. ''An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients.'' National Academy Press, Washington, D.C.

[3] Food Safety and Inspection Service. 1994. Nationwide Broiler Chickens Microbiological Baseline Data Collection Program: Broiler Chicken Sample Collection Procedures, 2/18/94. U.S. Department of Agriculture, Washington, D.C.

[4] Food Safety and Inspection Service. 1993. Nationwide Beef Microbiological Baseline Data Collection Program: Cow/Bull Sample Collection Procedures, 8/1/93. U.S. Department of Agriculture, Washington, D.C.

surveys for each species of livestock and poultry.

The *E. coli* performance criteria are expressed in terms of a statistical procedure known as a ''3-class attributes sampling plan'' applied in a moving window. This procedure specifies cutoffs (denoted m and M, with m<M) for quantitative *E. coli* levels so as to define three classes of results: acceptable, marginal, and unacceptable. The definitions are:

Acceptable—result ≤ m
Marginal—result > m and ≤ M
Unacceptable—result > M

Under this approach, m and M are defined in relation to the distribution of *E. coli* results for each slaughter class. The Agency has used as the starting point for establishing the cutoff for m the 80th percentile of current industry wide performance, in terms of *E. coli* levels, for each slaughter class. The starting point for establishing M is the 98th percentile of industry performance. Thus, if the criterion for any species were set precisely at those percentiles, a set of test results indicating performance in the 80th to 98th percentile range, according to FSIS's Nationwide Microbiological Baseline Data Collection Program results, would be deemed ''marginal,'' and, as discussed below, would raise a question about the adequacy of the establishment's process control. Expressed in another way, ''marginal'' results would be within the worst 20% of overall industry performance in terms of *E. coli* counts. Similarly, results worse than the 98th percentile (M) are within the worst 2% of overall industry performance. Any single result exceeding M is, therefore, deemed ''unacceptable.''

TABLE 1.—DISTRIBUTION OF E. COLI BY SLAUGHTER CLASS

Percentile	Steer/heifer	Cow/bull	Broilers	Hogs
50th (median)	Negative*	Negative*	29 cfu/ml	Negative*
80th (m)	Negative*	Negative*	80	10 cfu/cm^2
90th	Negative*	10 cfu/cm^2	180	150
95th	10 cfu/cm^2	40	360	880
98th (M)	80	300	1100	6,800
99th	290	2200	3300	33,000

*Negative by the method used in the baselines which had a minimum detectable level of 5 cfu/cm^2 of carcass surface area.

Table 1 shows the level at which *E. coli* has been found on carcasses, by slaughter class as a percent of all such product. For example, the data show that 80% of broilers tested at or below 80 colony forming units per milliliter (cfu/ml), while 90% tested at or below 180 cfu/ml. More detailed descriptions of the distribution of numbers of *E. coli* found per carcass species are provided in FSIS's baseline reports.

To make the criteria as simple and easy to use as possible, consistent with the accepted laboratory practice of diluting samples successively by factors of 10 to obtain bacteria counts, FSIS has elected to express the criteria in terms of powers of 10 (i.e., 10, 100, 1000, etc.). As shown in Table 2, this results in m and M being the closest power of 10 to the actual numbers estimated for the 80th and 98th percentiles from the baseline data.

Because the Agency's baseline survey work on turkeys is still underway, no *E. coli* criterion is being established at this time for that slaughter class.

TABLE 2.—M AND M VALUES FOR E. COLI PERFORMANCE CRITERIA

Slaughter class	m	M
Steer/Heifer	(1)	100
Cow/Bull	(1)	100
Broiler	100	1000
Hogs	10	10,000

[1] Negative.

It should be noted that ''negative,'' in this context, is defined by the sensitivity of the method used in the Baseline Surveys, which was 5 cfu/cm^2 of carcass surface area for cattle and hogs.

FSIS is requiring the use of an analytic method approved by the Association of Official Analytic Chemists or any method validated by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

FSIS has concluded that, at some point, the number of samples testing in the marginal range raises a significant question about the adequacy of an establishment's process control, and has defined that point for purposes of these criteria as more than 3 results above m within any consecutive 13 samples tested. This point was established based on the following analysis.

There occasionally will be test results that exceed the acceptable level, m, because of variations or aberrations in establishment performance, sampling, etc., that do not reflect the state of overall process control. FSIS believes that the performance criteria and approach to evaluating test results should avoid raising a significant process control question on the basis of chance results, but should be sensitive enough to provide a reasonably high likelihood of detecting performance that falls significantly short of the national baseline levels. FSIS has decided that it is appropriate to evaluate test results in a manner that ensures that there is an 80% probability that establishments actually operating at the acceptable performance level will achieve results that are deemed to satisfy the criteria. This is the same statistical approach FSIS took in its proposed approach to evaluating an establishment's *Salmonella* test results, using the moving window approach to evaluating process control verification tests (see pages 6798–6805 of the Pathogen Reduction/HACCP proposal).

Using this approach, it can be predicted statistically that slaughter establishments that are operating at the acceptable performance level reflected by m will, with an 80% probability, have three or fewer results above m (denoted as c) within every 13 samples tested (denoted as n). FSIS will require slaughter establishments to record and evaluate *E. coli* results in a ''moving window'' of 13 consecutive results. A moving window provides a continuous picture of establishment performance and is the preferred statistical approach for assessing ongoing processes (as opposed to sampling specific lots of product for contaminants). Thus, the presence of more than three marginal results within any 13 consecutive samples, or the ''window,'' will be indicative of an operation failing to meet the criteria.

Use of a different probability level, such as a 70% or 90% probability of getting acceptable test results if establishments are operating at the specified level would result in different values for c and n (namely, c=3 and

n=15 using the 70% probability level, and c=3 and n=10 using the 90% probability level). Using 70% as the statistical criterion for setting c and n would result in too many chance failures of the criteria, while using 90% would make it too difficult to detect potential process control problems. It is the judgment of the Agency that use of the 80% probability level strikes a reasonable balance.

In summary, if the results of one test are above M, or if more than 3 of 13 test results are above m, a significant question is raised as to whether the establishment is maintaining adequate process control and will trigger further review of establishment process control. FSIS stresses again that these *E. coli* criteria are guidelines, not regulatory standards. Ideally, each establishment will develop its own equally or more effective criteria for process control based on its own data and/or industry-developed benchmarks. FSIS encourages establishments, in the context of their HACCP plans, to apply their own, establishment-specific criteria to ensure process control.

FSIS also is inviting comment on the approach it has taken to expressing its *E. coli* performance criteria for verifying process control. FSIS recognizes that there is more than one possible approach and welcomes comments and suggestions.

Sampling Frequency for E. coli Testing

FSIS has chosen to use production volume as the basis for determining the frequency at which establishments will conduct testing for *E. coli*. In the proposed rule, FSIS proposed to require all slaughter establishments and establishments producing ground meat and poultry, regardless of size or volume, to conduct one test for *Salmonella* each day. This was based on the premise that verifying that a process is ''in control'' is more a function of specific establishment characteristics than the amount of product being produced. However, commenters suggested and FSIS recognizes that there may be striking differences in the ways in which high and low volume establishments operate, which can influence the ability of the establishment to keep processes in control. High volume establishments may receive animals for slaughter from a number of different sources for each day's production; there may be several shifts, and production personnel are often more transient; there may be multiple supervisors; and there may be much greater complexity in the overall slaughter process. In contrast, a low volume establishment will have a smaller and possibly more stable work-force, often supervised by an owner-operator, and may employ relatively simple procedures that are performed consistently over time. This does not negate the need in low volume establishments for microbial verification of a HACCP plan; however, under these circumstances it may not be as essential for very low volume establishments to undertake daily microbial testing, as initially proposed. By adopting a volume-based system, the testing frequency will, by definition, be highest in large establishments producing the most product, while the number of tests will be minimized in smaller establishments.

The majority of commenters who opposed daily testing stated that such a testing requirement would place an unfair cost burden and have a negative financial impact on small establishments, as it would require the same expenditure for testing by establishments that slaughtered one or two animals per day as those slaughtering several thousand daily. It was also noted that there is a public health consequence to the proposed approach. If a process control problem detectable by microbial testing existed in a high volume establishment that tested only once a day, a great deal more potentially contaminated product would be produced and distributed before enough microbial tests were performed to show the problem existed than would be the case in a small volume establishment. These issues are addressed by the switch to a volume-based testing system.

There is no single method for determining the frequency of microbial testing within a volume-based testing system that will be equally effective in all establishments. Testing frequencies are ideally determined on an establishment-by-establishment basis, taking into account a number of variables, including differences in sources of raw materials, the type and nature of the process, and the consistency of microbial test results over time. Nonetheless, for both public health and process control verification reasons, FSIS considers it necessary and reasonable to require a minimum frequency of testing sufficient to result in completion of at least one *E. coli* test window (13 samples) per day in the highest volume establishments for each species. This will provide a daily set of results adequate to verify process control in the highest volume establishments. Accumulation of results over a longer period of time will be an acceptable basis for verifying process control in lower volume establishments.

Based on these principles and conclusions, the required minimum frequencies for *E. coli* testing for each slaughter species are as shown in Table 3.

TABLE 3.—E. COLI TESTING FREQUENCIES

Cattle	1 test per 300 carcasses.
Swine	1 test per 1,000 carcasses.
Chicken ...	1 test per 22,000 carcasses.
Turkey	1 test per 3,000 carcasses.

The frequencies were derived by first rank-ordering all slaughter establishments by species based on total annual production. This ranking, which was based on data from FY 1993 and FY 1994, revealed that establishment production volumes vary widely and that there are appreciable differences in the concentration of business among the industries. In cattle slaughter, 12 of 912 establishments accounted for over 42% of production, with the smallest of these slaughtering about one million head annually. On the small volume end, 620 establishments slaughtered fewer than 1000 head annually and together accounted for about one-half of one percent (0.5%) of national slaughter production. By contrast, there are ten or fewer very low volume establishments slaughtering chickens, and production is spread more evenly over the 240 establishments on the FSIS FY 1994 inventory of establishments. 42 of 240 slaughter establishments accounted for 40% of production.

FSIS has selected sampling frequencies so that in the subgroup of establishments accounting for 99% of total production for each species, the 5% of establishments with the highest production volume would each have to conduct a minimum of 13 *E. coli* tests, or at least one complete test window, each day. In addition, with these frequencies, 90% of all cattle, 94% of all swine, 99% of all chicken, and 99% of all turkeys will be slaughtered in establishments conducting a minimum of one *E. coli* test per day.

The above frequencies notwithstanding, FSIS has concluded that all establishments must conduct sampling at a frequency of at least once per week to provide a minimum, adequate basis for process control verification using *E. coli* testing. However, establishments with very low volumes, annually slaughtering no more than 6,000 cattle, 20,000 swine, or a combination of such livestock not to exceed a total of 20,000 with a maximum of 6,000 cattle, or 440,000 chickens or 60,000 turkeys (or a combination of such poultry not to

exceed a total of 440,000, with a maximum of 60,000 turkeys), will be required to sample once per week only until a sampling window that verifies process control has been completed and the results indicate that the slaughter process is under control. Establishments slaughtering more than one species would sample the species slaughtered in greater number. Once these criteria have been met, these establishments will be required to complete a new sampling window that verifies process control only once each year, in the 3-month period of June through August, or when a change has been made in the slaughter process or personnel.

The Agency is permitting these very low volume establishments to conduct as few as 13 tests per year, in part because of their relatively simple and stable production environments. The slaughtering equipment in many cases may consist merely of a skinning bed, hoist, bonesaw (for poultry establishments, a small scalding tank, small defeathering device), and/or several types of knives. There are fewer personnel and there is less turnover in general. Of course, these establishments do change. Should there be any substantial changes in installed equipment or personnel, a new sampling window must be completed. These establishments must also complete a successful sampling window annually, regardless of whether there have been any substantial changes, in order to verify that the performance criteria continue to be met. Many small, nonsubstantial changes, in aggregate, may have an impact on process control. This annual testing must be conducted during the summer months of June through August, when there is a seasonal peak in the occurrence of foodborne diseases attributable to the major bacteria pathogens. Published and summary reports of Centers for Disease Control and Prevention (CDC) outbreak and sporadic disease surveillance have documented this seasonal trend for *Salmonella spp*.[5,6] and for *Campylobacter jejuni/coli*.[7] Although national surveillance for *E. coli* O157:H7 is relatively new and data are not available, Washington State surveillance has documented a similar seasonal trend for that pathogen.[8] The proposed requirement of one *Salmonella* sample per day would have assured testing during this period.

Therefore, the regulation specifies that when sampling and testing is done annually, instead of continually, it be conducted within a 13-sample window between June and August each year. This annual sampling must occur during this period, regardless of when other sampling windows may have occurred. Completing a successful sampling window annually will verify that the slaughter process continues to meet the performance criteria or will point to the need to reassess and revise the HACCP plan.

Another reason for this approach to very low volume establishment testing is that the total risk of exposure to enteric pathogens from product produced at such establishments is assumed to be small and roughly proportional to the amount of product produced. Eighty-one percent of establishments slaughtering cattle would meet this low volume criteria; however, these establishments together supply only 1.5% of the total national production. Further, establishments meeting these low volume criteria constitute 86% of all swine establishments, accounting for 1.3% of overall production. Thirteen percent of all establishments slaughtering chicken would meet this low volume requirement; however, these establishments together supply only 0.05% of total national production. Similarly, 42% of all turkey establishments are low volume establishments accounting for only 0.1% of production.

FSIS intends that establishments operating under a validated HACCP system use microbial testing in their process control verification activities, and is requiring that slaughter establishments under HACCP use *E. coli* testing for that purpose. As noted above, however, the Agency acknowledges that there may be other, perhaps equally effective alternative approaches for determining sampling frequencies for *E. coli* testing for process control verification in slaughter establishments with a carefully designed HACCP system. The Agency is aware that comparable models have been developed in the context of quality assurance programs. These models, however, are part of programs that, like HACCP, involve more than mere statistical sampling, and usually are much more oriented to specific establishment/process/product combinations. Such models cannot easily be transferred to a nationwide collection of producers of a product, each with unique characteristics. The frequency rule established in this regulation recognizes the relevance of establishment characteristics in the area of verification, as in other facets of the HACCP plan, and therefore allows slaughter establishments to alter frequencies as appropriate for their circumstances when they institute HACCP. That is, slaughter establishments under HACCP may use a sampling frequency other than that provided for in the regulation, if the alternative sampling frequency is an integral part of the establishment's HACCP verification procedures and if FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls. Establishments electing to institute HACCP prior to the dates required may use an alternative sampling frequency upon presentation to FSIS of data demonstrating the adequacy of that sampling frequency for verification of process controls to prevent fecal contamination.

Establishments currently using an alternative *E. coli* sampling frequency for process control purposes, but not yet under a HACCP plan, will have to test at the frequencies specified in the regulation unless they have been granted an exemption by FSIS. However, after consideration of comments received on this rule that may result in protocol changes affecting all establishments, and publication of a Federal Register document addressing the comments, FSIS will consider requests for such exemptions on a case-by-case basis, upon the timely submission to FSIS of data demonstrating the adequacy of the alternative frequency for verification of process controls to prevent fecal contamination.

Sampling and Analytical Methodology

Carcasses within the same establishment and in different establishments must be sampled and analyzed in the same manner if the results are to provide a useful measure of process control. Such consistency also will facilitate FSIS verification activities. As discussed below, the performance criteria are applicable to each type of carcass, industry-wide, based on FSIS's national baseline survey data. Because each establishment's performance is measured against the

[5] Bean, N.H. and P.M. Griffin. 1990. Foodborne Disease Outbreaks in the United States, 1973–1987. J. Food Protection. 53:804–817.

[6] Centers for Disease Control and Prevention. 1995. Salmonella Surveillance, Annual Tabulation Summary, 1993–1994. U.S. Department of Health and Human Services, Public Health Service, Atlanta, GA.

[7] Tauxe, R.V., N. Hargrett-Bean, C.M. Patton, and I.K. Wachsmuth. 1988. *Campylobacter* Isolates in the United States, 1982–1986. MMWR. 37 (SS–2):1–13.

[8] Ostroff, S.M., J.M. Kobayshi, and J.H. Lewis. 1989. Infections with *Escherichia coli* O157:H7 in Washington State. JAMA 262(3):355–359.

performance of all surveyed establishments producing the same kind of product, it is essential that all like establishments adhere to the same basic sampling and analysis requirements.

Each establishment is responsible for having written sampling procedures that are to be followed by a designated employee or agent. Samples are to be taken randomly at the required frequency. If an establishment runs more than one line, the lines from which samples are to be taken also are to be selected randomly. Samples from livestock carcasses are to be collected by a nondestructive method that requires a commercially available sampling sponge to be rubbed on the carcass surface after the carcass has been chilled in the cooler for 12 hours or more after slaughter. Establishments are required to take samples from three sites on each carcass. These three sites are the same ones that were used by FSIS when conducting the baseline studies for cattle and swine. On cattle carcasses, establishments will take samples from the flank, brisket, and rump areas; on swine carcasses, samples will be taken from the ham, ''belly,'' and jowl areas. The sponge is to be placed afterwards in an amount of buffer to transfer any *E. coli* to a solution, which then is analyzed for *E. coli.* Samples from poultry carcasses will be collected by taking whole birds from the end of the chilling process, after the drip line, and rinsing them in an amount of buffer appropriate for the type of bird being tested.

The sponge sampling technique to be used on swine and cattle carcasses has been subject to many studies. A sponge technique has been reported by Dorsa *et al.*[9] and others, including Gill *et al.*[10], as an acceptable means of in-plant sampling to detect fecal contamination.

The excision method for sample collection would not be acceptable for routine sampling to verify process control because this defaces the carcass, and some establishments would be required to sample 13 carcasses per day. Instead, for both cattle and swine carcasses, the sponge method requires that 100 cm^2 at each of the three sites be sampled by swabbing, for a total area of 300 cm^2 compared to the 60 cm^2 area of excised tissue analyzed in the baseline studies for cattle and swine. The results would still be reported on a square centimeter basis. The larger sampling area for the swabbing method is expected to provide results comparable to the excision technique.

The exact correlation between the sponging technique and the excision technique used during the baseline surveys is being assessed by ARS. Currently available results indicate a high degree of correlation between the two. These studies and any other new microbial sampling data will be made available to the public. This sponging technique will also be used in the FSIS *Salmonella* program. FSIS is continuing to improve the sponging technique and welcomes comments.

FSIS considered providing that samples be taken from only one site on livestock carcasses: from the brisket on cattle and the belly area on swine. Sampling from one site has advantages. It would be less labor intensive. Further, sampling from one site might pose fewer worker safety problems than sampling from three sites because, for the latter option, a ladder generally is needed to reach the rumps of the suspended carcasses. Nonetheless, FSIS has determined that slaughter establishments must take samples from the three sites from which samples were drawn during the baseline studies or programs in the absence of data demonstrating that one-site sampling also will provide results comparable to the baseline survey data. The Agency invites comments on its requirement that establishments collect samples from the specified three sites on swine and cattle carcasses and the adequacy of alternative sampling approaches.

Samples may be analyzed in either the establishment's own laboratory or a commercial laboratory. Samples must be analyzed by a quantitative method of analysis for *E. coli.* The method must be approved by the Association of Official Analytic Chemists or validated by a scientific body in collaborative trials against the three tube most probable number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

FSIS has developed and is publishing as an appendix to the document guidelines that provide additional, detailed information on how best to sample, test, record, and interpret results for *E. coli* under this regulation. FSIS invites comment on these guidelines.

Recordkeeping

Results of each test must be recorded, in terms of colony forming units per milliliter (cfu/ml) for poultry carcasses or per square centimeter (cfu/cm^2) for livestock carcasses, on a process control chart or table that permits evaluation of the test results in relation to preceding tests in accordance with the applicable criteria. These records must be maintained at the establishment for 12 months and must be made available to Inspection Program employees on request. Inspectors will monitor results over time, to verify effective and consistent process control.

Use of E. Coli Test Results by Establishments

As discussed in preceding sections, establishments slaughtering livestock or poultry are required to use *E. coli* testing and evaluation of the results to verify the adequacy of their process controls for fecal contamination. Any test result in the marginal range (above m) indicates to the establishment that there is a potential problem in its processing control that may require attention. If the number of test results above m exceeds the specific number allowed, c (3, for all species), in the specific number of consecutive tests in the moving window, n (13 for all species), the establishment has failed to meet the performance criteria, and a significant question has been raised about the adequacy of the establishment's process controls for fecal contamination. Review of the process by the establishment and necessary corrective actions are strongly suggested.

Results above the upper value M are unacceptable and should trigger immediate establishment review of slaughter process controls to discover the cause of the failure and to prevent recurrence, and, if a product has been affected, to consider the status and proper disposition of the product as the circumstances dictate.

Use of E. coli Test Results by FSIS

FSIS personnel, like establishment personnel, will use the *E. coli* test results to help assess how well the establishment is controlling its slaughter and dressing processes. FSIS will compare establishment test results to the applicable *E. coli* performance criterion. A single failure to meet the criterion does not by itself demonstrate a lack of process control or product adulteration, but it will trigger greater inspection activity to establish that all applicable sanitation and process control requirements are being met and product is not being adulterated. Inspectors may make additional visual inspections of products and/or equipment and facilities, collect samples for FSIS laboratory analysis, and retain or condemn product, as appropriate. In addition, Sanitation

[9] Dorsa, W.J., C.N. Cutter, G.R. Siragusa. 1996. Evaluation of Six Sampling Methods for Recovery of Bacteria from Beef Carcass Surfaces. Letters in Applied Microbial. 22:39–41.

[10] Gill, C.O. J.C. McGinnis, M. Badoni. 1996. Assessment of the Hygienic Characteristics of a Beef Carcass Dressing Process. J. Food Protection 59(2):136–140.

SOP's and HACCP records will be reviewed, as appropriate. Failure to meet the criterion may also result in the establishment being selected for intensified Agency testing for *Salmonella* under the pathogen reduction performance standard sampling program; and, if the establishment produced ground beef, its product could be targeted in the *E. coli.* O157:H7 ground beef testing program.

The *E. coli* test results will be used by FSIS, along with all other relevant data and observations, including past establishment performance, to determine whether a slaughter establishment is meeting its process control responsibilities. Repeated failures to meet the criterion would lend support to a finding that the establishment's process controls are inadequate. Failure to maintain adequate process control will result in suspension and withdrawal of inspection, as appropriate. Such actions will be made in accordance with rules of practice that will be adopted for those proceedings.

After a slaughter establishment implements HACCP, the *E. coli* testing program will continue as a HACCP verification activity. Isolated or occasional failures to meet the *E. coli* performance criterion may indicate that establishment personnel need to take corrective actions spelled out in their HACCP plan. Repeated failures to meet the criterion will result in FSIS focusing its verification oversight on relevant CCP's, which could lead to the need for HACCP plan reassessment by the establishment, as well as other inspection and compliance related activities that may be appropriate, as discussed above.

Implementation Timetable

Six months from this publication date, establishments that slaughter livestock or poultry will be required to begin sampling and testing for *E. coli* at the volume-based rates described above. From that time, those establishments that do not test or fail to keep records of results as prescribed by the regulation will be subject to withdrawal of inspection in accord with the procedures set forth in 9 CFR 335.13 or 381.234. After another six months, i.e., 12 months after publication of this final rule, after establishments have had an opportunity to gain experience in conducting this testing, recording the results, and using the data to verify and improve process control, FSIS personnel will incorporate the review of establishment *E. coli* test results into its inspection routine.

In considering the timeframe for implementing the *E. coli* testing requirement, FSIS has taken into account the practicality of initiating such testing in a large number of establishments, the potential utility of the resulting data to establishments as they prepare for HACCP implementation, and the added consumer protection of having establishments, particularly those scheduled to implement HACCP towards the end of the implementation timetable, initiating testing and evaluating results against the process control performance criteria. FSIS is aware that many establishments, especially large ones, already use microbial testing as a means of verifying their process control systems; many may already be testing for generic *E. coli.* Some of those establishments may already have HACCP plans in place as well. Establishments performing microbiological testing and already working under HACCP plans have found that such testing is an important element in conducting a hazard analysis, validating HACCP plans, and verifying the ongoing effectiveness of HACCP systems.

For establishments that are not already performing microbiological testing and not operating under HACCP plans, the data will be valuable in revealing how well or poorly their slaughter process is performing in microbiological terms, when compared against the microbial characteristics of a large portion of national production, and will provide an indication of whether immediate actions are required to prevent product adulteration and protect food safety. In addition, such data, when accumulated over a period of time, will contribute to the conduct of hazard analyses and selection of process control measures. Collection of these data will provide benchmarks for each establishment as it begins to understand the food safety implications of its processes and how to improve them.

In the meantime, FSIS personnel, using the performance criteria as benchmarks for overall industry performance in terms of the number of *E. coli* organisms found on carcasses at a specific point in the slaughter process, will be able to review establishment data and other evidence to determine if each establishment is achieving an acceptable level of performance.

Request for Comments

The Agency is soliciting additional comment and information on a number of technical issues concerning the protocols for *E. coli* testing, and on that basis will consider adjusting those protocols prior to the effective date. In particular, two concerns have been raised on the issue of the rule's statistical framework: 1) the representativeness of the proposed sample collection, and 2) the levels and distribution of *E. coli* on carcasses and the ways in which these levels affect the utility of the proposed testing protocol.

Because poultry slaughter establishments must collect samples with a whole bird rinse, the representativeness of the sampling site is not an issue; the entire bird is being sampled. FSIS used this technique when collecting baseline data and therefore, establishment data should be comparable to baseline survey data. Further, greater than 99 percent of broiler carcasses in the national baseline survey had detectable *E. coli.* Generic *E. coli* testing data therefore clearly will be useful to poultry slaughter establishments as they initiate HACCP and begin to verify the associated process control procedures. *E. coli* testing procedures for poultry required by this rule comport well with the available scientific data and discussions held as part of the public comment process.

More difficult issues arose in developing *E. coli* sampling procedures for cattle and swine carcasses. Part of the concern, as discussed, stems from the fact that a whole carcass rinse is impossible with a large carcass, and thus it is necessary to select specific sampling sites. Selections of sites, in turn, may influence results, particularly if generic *E. coli* is not randomly distributed on the carcass. Site selection may also influence the usefulness of resultant data. For example, the appropriate response to an elevated generic *E. coli* level on the rump of a beef carcass may be different from the appropriate response to an elevated generic *E. coli* level at the site of the midline incision. The Agency wants comments on the relative merits of a one-site versus three-site sampling approach.

Another concern revolves around the correlation between non-destructive and destructive sampling. The baseline surveys used destructive sampling, that is, culturing of tissue excised from the carcass. FSIS agrees with commenters that reasonable results can be obtained with a non-destructive swabbing technique for sampling. Preliminary data indicate that results obtained with a destructive and non-destructive sampling are comparable, although studies continue.

Another concern arises from the statistical basis for *E. coli* testing. In

particular, the levels of generic *E. coli* on cattle carcasses in the national baseline survey were low, with the majority of carcasses having no detectable *E. coli*. This could raise questions about the utility of the *E. coli* test results in evaluating process controls in establishments slaughtering cattle.

The principal utility of process control testing stems from the availability to a establishment of results over time from that establishment. The tracking of trends and identification of anomalous results permits isolation and correction of problem areas that might otherwise go unnoticed. FSIS has concluded that testing for generic *E. coli* is the appropriate and necessary means by which meat and poultry slaughter establishments must evaluate and verify the adequacy of their process controls. FSIS considers systematic measures to prevent and remove fecal contamination and associated bacteria, coupled with microbial testing to verify effectiveness, to be the state of the art in slaughter establishment sanitation. Microbial testing for bacteria that are good indicators of fecal contamination and the regular availability of test results will help to focus establishments on the effectiveness of their measures for preventing and removing fecal contamination and will provide information establishments can use in maintaining adequate process control. FSIS reached this conclusion upon its review of written comments received on the proposal and comments made at the scientific conferences and public meetings, as well as available scientific data, and has retabulated and reassessed its baseline data as it applies to the *E. coli* testing in the rule.

In the first reassessment, it was determined that the lower levels and more frequent negative test results of *E. coli* found on livestock, particularly steers and heifers, as compared to poultry in the baseline survey data does not undercut the utility of the *E. coli* criteria which are also based on the baseline survey data. FSIS tested the performance criteria in this rule by applying it to plant-specific test results obtained during the baseline surveys. FSIS looked at data from establishments for which at least 20 test results were available, and listed the results by collection date much as would be done by the establishments under the rule. The Agency found that about half of the establishments in each of the livestock slaughter categories fully met the criteria, which suggests that those establishments have good process controls for prevention of fecal contamination. The Agency also found that many establishments failed to meet the applicable *E. coli* criterion (any result above M, or more than 3 results above m out of the most recent 13 test results): 2 out of 30 steer/heifer establishments, 10 out of 34 cow/bull establishments, and 11 out of 31 market hog establishments failed to meet the criterion at least 20% of the time, suggesting that a significant number of livestock slaughter establishments should review and make adjustments to their process controls.

The Agency also made an assessment of whether the baselines show true differences in *E. coli* results among establishments that slaughter the same categories of livestock. The Agency did a statistical analysis of a hypothesis: percents positive are equal among establishments slaughtering the same category of livestock. The analysis involved comparing *E. coli* test results of pairs of establishments. This comparison showed wide ranges in the percents positive between establishments albeit smaller differences among steer/heifer establishments. The percents positive ranged between 0.0 to 27.1 for steer/heifer establishments, 0.0 to 45.2 for cow/bull establishments, and 2.2 to 97.1 for market hog establishments. The hypothesis, therefore, was rejected because the data showed significant differences in the prevalence of *E. coli* on carcasses of animals found in establishments slaughtering the same categories of livestock.

The retabulated data developed for these two analyses are available for viewing in the FSIS Docket Room (See **ADDRESSES**) as part of the administrative record of this rulemaking.

FSIS invites comments on the statistical frameworks it has used for *E. coli* testing and performance criteria. The Agency is open to the possibility that it might further improve its testing protocols prior to the implementation date, and is seeking additional relevant scientific and economic data. In particular, in light of the concerns noted above, FSIS is seeking additional data relating to the distribution of generic *E. coli* on cattle and swine carcasses, differences in *E. coli* levels within and between establishments, and the appropriateness of various data sets for establishing the proposed 80th and 98th percentile national criteria for generic *E. coli* levels on cattle and swine carcasses.

FSIS also requests comments and information addressing the following questions:

Are there alternative, equally or more effective risk based microbial sampling protocols that could be used for process control verification by establishments that slaughter cattle or swine?

Are there more appropriate anatomical sites for microbial testing than those adopted?

Are there alternative sampling frequencies that would elicit results more indicative of process control performance?

How could the proposed testing protocol be revised to better account for differing establishment characteristics and how can FSIS minimize the cost to establishments of *E. coli* testing without sacrificing testing effectiveness?

Are there worker safety concerns regarding sampling from difficult to reach carcass sites and, if so, how might they be mitigated?

Given that testing is based on production volume, are there effective approaches other than requiring very small establishments to conduct a minimal amount of testing during certain months of the year?

FSIS is aware that some individuals, companies, and trade groups have conducted research and have data on the various carcass sampling sites and associated levels of bacteria at these sites (carcass mapping). FSIS welcomes any information concerning *E. coli* and other microorganisms at various sites on carcasses.

FSIS has opted to establish performance criteria based on the levels and distribution of *E. coli* for the various slaughter classes. Some individuals and companies may have established their own criteria for process control verification. FSIS welcomes information on the rationales, sampling plans and protocols on which any such criteria are based, as well as data (or data summaries) collected under such protocols.

FSIS welcomes any new or unpublished research results or information that exists concerning the relationship between the presence of generic *E. coli* and the presence of other pathogenic microorganisms on cattle and swine carcasses.

FSIS specifically invites establishments currently conducting generic *E. coli* testing for process control verification to submit data regarding their costs, including labor and training costs, as well as testing costs per unit. FSIS will use this data to assess the merits of alternative testing protocols.

FSIS invites comments on how, and the extent to which, it should summarize and make available to the industry and public *E. coli* testing data made available to it under these regulations. Reports on the collective experiences of establishments with various characteristics could be useful to the industry, the Agency, and the public at large.

In light of these issues, in particular those reflecting continuing concerns

about the applicability of the national criteria to all affected establishments, the frequency and other parts of the testing protocols, and the statistical utility of the establishment's test results as a measure of process control, FSIS plans to conduct two public conferences. The first conference is planned to be held approximately 45 days into the 60 day comment period following publication of this rule. This public conference will be led by a panel of scientists from FSIS and other government agencies who will listen to testimony and review comments received on these technical issues and share their observations and opinions. FSIS will consider their input along with all comments received as the basis for any necessary technical amendments, which will be completed at least 30 days before the implementation date. The second public conference is tentatively planned for approximately 9 months following publication of this final rule. This conference would be an opportunity for the industry and others to discuss with FSIS new information based on about 3 months of testing experience that may bear on these same issues and might allow for further adjustments of protocols before FSIS inspectors are tasked, about three months later, with comparing test results to the national criteria as part of their inspection routine. FSIS will publish further, more detailed notice of these conferences in future issues of the Federal Register.

Pathogen Reduction Performance Standards

The pathogen reduction performance standards for *Salmonella* FSIS is establishing in this final rule complement the process control performance criteria for fecal contamination and *E. coli* testing.

The likelihood of product contamination by *Salmonella* is affected by factors in addition to the incidence or degree of fecal contamination, including the condition of incoming animals and cross contamination among carcasses during the slaughter process and further processing. Under HACCP, establishments will be expected to establish controls wherever practicable to address and reduce the risk of contamination with harmful bacteria. The pathogen reduction performance standards FSIS is establishing for *Salmonella* are an important step toward enabling FSIS and the establishment to verify the aggregate effectiveness of an establishment's HACCP controls in reducing harmful bacteria.

Rationale for Selecting Salmonella

In the future, FSIS may develop pathogen reduction performance standards targeting a number of pathogens. Initially, however, FSIS has developed pathogen reduction performance standards only for one—*Salmonella. Salmonella* is an enteric pathogen, which as a group cause most preventable illnesses associated with meat and poultry.

FSIS has selected *Salmonella* because: (1) it is the most common bacterial cause of foodborne illness; (2) FSIS baseline data show that *Salmonella* colonizes a variety of mammals and birds, and occurs at frequencies which permit changes to be detected and monitored; (3) current methodologies can recover *Salmonella* from a variety of meat and poultry products; and (4) intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product should be effective against other pathogens.

Basis for Performance Standards and Plans for Future Adjustments

The pathogen reduction performance standards for *Salmonella* are based on the current prevalence of *Salmonella*, as determined from FSIS's baseline surveys. Current prevalence percentages based on the data from these surveys are listed in Table 4 and in the regulations (new §§ 310.25(c)(3)(ii) and 381.94(c)(3)(ii)) under the column headed ''Performance Standard.'' This is the performance standard that establishments must achieve, not on a lot-by-lot basis, but consistently over a period of time through appropriate and well-executed process control.

This is the same approach to setting the ''interim targets for pathogen reduction'' that FSIS proposed in its Pathogen Reduction/HACCP proposal. As explained in the preamble to that proposal, basing the performance standard on the national baseline prevalence means that some establishments are already meeting or exceeding the standard, while other establishments are not. FSIS believes that it is feasible for all establishments to meet or exceed the current baseline prevalence of contamination with *Salmonella,* through careful process control to prevent contamination and incorporation of readily available food safety technologies and procedures to remove contamination. The feasibility of achieving this standard is demonstrated by the fact that many establishments are already doing so.

The Agency believes that most establishments maintaining sanitary conditions under their Sanitation SOP's and operating under validated HACCP plans, as provided for elsewhere in this regulation, will be able to meet the pathogen reduction performance standards without major new costs. For example, HACCP plans for slaughter establishments are expected to address the condition of incoming animals, and may provide for more systematic control of relevant processes or interventions, such as the cleaning of animals or carcasses before evisceration. HACCP systems should, therefore, result in many establishments improving the microbial profile of their finished raw products.

Slaughter establishments concerned that they might not meet the pathogen reduction performance standard have available a wide range of technologies shown to reduce the levels of pathogens that may be on the surface of carcasses. As discussed in some detail in the proposed rule, antimicrobial treatments normally include washes or sprays that use either hot water or a solution of water and a substance approved by FSIS for that use. Such substances include acids (lactic, acetic, and citric), trisodium phosphate (TSP), and chlorine. In addition, FSIS has recently established that spray-vacuum devices that apply pressurized steam or hot water to beef carcasses and immediately vacuum it up also are effective in reducing bacteria on carcasses.

Establishments producing raw ground product from raw meat or poultry supplied by other establishments cannot use technologies for reducing pathogens that are designed for use on the surfaces of whole carcasses at the time of slaughter. Such establishments may require more control over incoming raw product, including contractual specifications to ensure that they begin their process with product that meets the standard, as well as careful adherence to their Sanitation SOP's and HACCP plan.

By basing its *Salmonella* performance standards on the current national baseline prevalence for each major species and product class, FSIS is applying a uniform policy principle: all establishments must achieve at least the current baseline level of performance with respect to *Salmonella* for the product classes they produce. This policy is based on the public health judgment that reducing the percentage of carcasses with *Salmonella* will reduce the risk of foodborne illness, and on the regulatory policy judgment that establishing for the first time a clear standard for Salmonella, in conjunction with the implementation of HACCP, will lead to significant reductions in

contamination rates. This policy is not based on a quantitative assessment of the risk posed by any particular incidence of *Salmonella* contamination or the determination of a ''safe'' incidence or level. There is not currently a scientific basis for making such assessments or determinations.

FSIS recognizes that this approach results in a range of performance standards among the various product classes (see Table 4). For example, the current *Salmonella* prevalence for broilers is 20 percent, while the current prevalence for steers and heifers is 1 percent. This range reflects the current level of performance for each class of product, as reflected in the FSIS baseline surveys.

FSIS intends to revise its *Salmonella* performance standards periodically as new baseline prevalence data become available and in furtherance of the Agency's goal of reducing the risk of foodborne illness. FSIS will periodically repeat its baseline studies to assess the overall progress of the pathogen reduction effort. Also, as indicated below in the discussion of the FSIS testing strategy, FSIS will be conducting extensive *Salmonella* testing to ensure compliance with the pathogen reduction performance standards. If the data from this testing or future baseline surveys justify revision of the performance standards, FSIS will promptly publish such revisions for public comment in the Federal Register. FSIS anticipates revision of these performance standards downward as justified by progress in pathogen reduction and demonstrated reductions in the national baseline prevalence of *Salmonella.* In making such adjustments, FSIS will take into account the state of scientific knowledge, available technology, feasibility, and public health benefits to be achieved. FSIS will also consider the current level of industry performance with respect to *Salmonella* prevalence in particular classes of livestock and poultry. It is anticipated that such adjustments would more likely occur in classes with the highest prevalence. FSIS originally proposed to call these performance ''interim'' standards or targets. The final rule removes that language.

Approximately 15 months after the publication of this final rule, FSIS will convene a public conference to review available *Salmonella* data and discuss whether they warrant refining the *Salmonella* performance standards. Prior to the conference, FSIS will make available the data resulting from the pre-implementation phase of the FSIS *Salmonella* testing program. FSIS also will take advantage of this conference to receive public input on the *E. coli* testing program. FSIS will extend an invitation to all interested parties.

Additionally, FSIS intends to work closely with other Federal agencies and the scientific community to improve the scientific basis for establishing food safety performance standards for microbial pathogens. In particular, the Executive Office of the President, Office of Science and Technology Policy, will oversee a task force to determine what research and data collection are needed to develop a workable approach to quantitative risk assessment for foodborne pathogens and determine the most cost-effective way of conducting the necessary research. FSIS and other USDA agencies will participate in this government-wide task force.

Determining Compliance With the Standard

The pathogen reduction performance standards specify for each species and category of raw product a maximum number of positive test results (c) permitted to be found in a specified number of samples (n) for each class of raw product before the establishment will be deemed to be exceeding the performance standard. The standards were determined by first calculating for each category of product tested in the FSIS national baseline programs and surveys the percentage of *Salmonella* positives nationwide. This is, in effect, the performance standard that must be achieved consistently by each establishment over time. Then the number of samples to test (n) and the number of positives to allow from among those samples (c) were calculated to provide approximately an 80% probability of passing when the establishment is operating at the national baseline prevalence of *Salmonella* positive results, i.e., just within the performance standard. As discussed in the preamble to the Pathogen Reduction/HACCP proposal and above with respect to *E. coli* testing, the statistical criteria for evaluating *Salmonella* test results balance the need to prevent establishments from failing to meet the standard, based on chance results, and the need to ensure both that violations are readily detected and that establishments have an incentive to improve their performance beyond what is minimally required by the standard. The resulting values for the pathogen reduction performance standards are shown in Table 4.

TABLE 4.—PATHOGEN REDUCTION PERFORMANCE STANDARDS

Class of product	Performance standard (percent positive for *Salmonella*) (%)	Number of samples tested (n)	Maximum number of positives to achieve standard (c)
Steers/Heifers	1.0	82	1
Cows/Bulls	2.7	58	2
Ground Beef	7.5	53	5
Fresh Pork Sausage	*NA	*NA	*NA
Broilers	20.0	51	12
Hogs	8.7	55	6
Ground Turkey	49.9	53	29
Ground Chicken	44.6	53	26
Turkeys	*NA	*NA	*NA

* Not available at this time.

FSIS has concluded that, for purposes of this rulemaking, it should rely only on FSIS baseline data for determinations of the prevalence of bacteria on which it is establishing standards. The proposal discussed the possibility of relying on other data sources, such as industry surveys or other reports in the scientific literature. No such data were

submitted to FSIS in response to the proposal, and FSIS has concluded that those alternative data sources are not likely to provide the nationwide, objective data that are needed for the Agency's regulatory purpose of establishing performance standards. FSIS will consider modifications of the scope and approach to these surveys and additional data sources, as the needs of public health dictate, but will continue to rely only on data that are gathered with appropriate scientific rigor.

FSIS has completed its baseline survey work and has issued reports on its findings for Steers/Heifers, Cows/Bulls, Broiler Chickens, Market Hogs, Ground Beef, Ground Chicken, and Ground Turkey. Copies of these reports are available for inspection in the FSIS Docket Room (see **ADDRESSES**).

FSIS is currently conducting the fresh pork sausage survey and will begin the Baseline Program for turkeys soon. Therefore, performance standards for fresh pork sausage and turkeys cannot be established at this time. The performance standards for these two classes of products will be published for public comment once FSIS's reports on the data are available.

FSIS will determine an establishment's compliance with the applicable pathogen reduction performance standard by taking the indicated number of samples, generally at the rate of one or more per day, testing each sample for *Salmonella,* and determining whether the number of positive results is above the maximum permitted for that product in the regulation.

FSIS has established performance standards for *Salmonella* on carcasses and on raw products derived from meat and poultry. Because *Salmonella* is more likely to be present on raw, ground, or comminuted products than on the carcasses from which they are derived, raw, ground, or comminuted product ordinarily will be the focus of FSIS compliance testing in those establishments that both slaughter and produce raw ground product.

The pathogen reduction performance standard applies to establishments, not to individual products. As discussed, microbiological testing of raw products for purposes of routinely separating adulterated from unadulterated products is impractical at this time. The pathogen reduction standard for *Salmonella* requires testing of products not for purposes of determining product disposition (although in some circumstances it may contribute to additional inspection or compliance activities that do), but rather as a measure of the effectiveness of the process in limiting contamination with this particular pathogen. If an establishment fails to meet the standard, it must institute corrective actions to lower the incidence of *Salmonella* on all such product it produces as measured by subsequent testing, or, ultimately, it must cease producing that product. The FSIS enforcement strategy is further discussed below.

FSIS Testing Strategy

FSIS's *Salmonella* testing program will be implemented in two phases, a pre-implementation phase and a compliance phase. The pre-implementation phase will begin approximately three months after publication of the final rule and initially will consist of an establishment-by-establishment survey of the slaughter establishments represented in the National Microbiological Baseline Data Collection Programs. These establishments account for approximately 99 percent of the total production volume for each of the major species slaughtered nationwide. The testing in each slaughter establishment will be conducted in a manner designed to provide a reliable picture of the establishment's performance throughout a 12-month period, in relation to the pathogen performance standard applicable to the species being slaughtered. It is anticipated that initially FSIS will take approximately 250 samples per establishment over a one-year period, with testing to be completed before the implementation date for the standard in each establishment.

FSIS will also conduct pre-implementation testing in ground product establishments and in establishments that account for the remaining one percent of production and that were not included in the FSIS baseline surveys. This testing will be conducted in a manner and at a level that takes into account the size and nature of the establishments involved. FSIS will provide more detail on this testing soon in a separate notice.

This pre-implementation testing will inform both the establishments and FSIS, prior to the actual enforcement of the performance standards, whether each establishment is already meeting the standard, is close to meeting the standard, or requires substantial improvement to meet the standard. As with all FSIS testing done to check compliance with the pathogen reduction standards, the testing results will be provided to the establishment by FSIS. These testing results will assist establishments in designing and validating their HACCP plans as needed to ensure that products meet pathogen reduction performance standards. This information also will assist FSIS to more effectively target its compliance testing after the standards go into effect, as discussed below. This FSIS-generated data on the prevalence of *Salmonella* on inspected products will be available to the public.

Upon the implementation of HACCP, and upon publication of Federal Register documents concerning the pathogen reduction performance standards for which baseline survey reports have not yet been published, FSIS will initiate phase 2, the compliance phase, of its *Salmonella* testing program in affected establishments. As an integral part of its overall responsibility for food safety, FSIS will conduct an ongoing testing program to determine compliance with the *Salmonella* performance standard for all classes of livestock and poultry. In addition, FSIS will conduct a program of targeted testing where warranted. The frequency and intensity of this testing will be determined based on past establishment performance, the establishment's own generic *E. coli* test results, FSIS inspectional observations, reports of illness associated with product produced at an establishment, the results of *Salmonella* testing during the pre-implementation phase, previous failures to meet the performance standards, and other factors.

The costs to FSIS of this testing for *Salmonella,* estimated to be approximately 2 million dollars annually, are addressed in the Final Regulatory Impact Analysis of this rule.

FSIS Testing Methods

Details of the sample collection and testing procedures the Agency will be using are in Appendix E, ''FSIS Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products.''

FSIS Enforcement Strategy

The objective of FSIS's enforcement policy with respect to microbial testing is to achieve compliance with the regulations. With respect to *Salmonella,* the Agency's goal is to achieve pathogen reduction by ensuring that all slaughter and ground product establishments meet the performance standards established by FSIS. FSIS intends to achieve this goal through an enforcement strategy based on the two-part testing program mentioned above: the ongoing testing, which will include all establishments at some fixed interval, irrespective of performance;

and targeted testing focusing on establishments unable to meet the *Salmonella* performance standard when tested by FSIS or for the other reasons discussed above.

The *Salmonella* enforcement strategy will embody an objective, uniform systems approach to ensure that it is administered and applied in a fair, equitable, and common-sense manner. The Agency will carefully monitor and adjust its enforcement program on an ongoing basis to ensure that its enforcement activities reflect these principles while ensuring food safety.

If ongoing or targeted testing in an establishment indicates the performance standard is not being met, FSIS will decide whether to conduct follow-up testing on the basis of several factors. If an establishment with *Salmonella* test results marginally above the limit takes corrective action, FSIS could judge, based on the establishment's actions and other factors relevant to ensuring food safety, that immediate follow-up testing is not necessary. If, however, that establishment were to take inadequate corrective action after failing to meet the *Salmonella* performance standard, or if it simply ignored that failure, FSIS will conduct a second series of tests. FSIS will invariably conduct further testing at all establishments whose test results significantly exceed the standard.

If an establishment fails the second, targeted series of FSIS-conducted tests, the establishment will be required to reassess its HACCP plan for the tested product, modifying the plan as necessary to achieve the *Salmonella* performance standard. If the establishment fails to modify its HACCP plan as necessary, or if it fails the third series of targeted tests, FSIS will suspend inspection services. The suspension will remain in effect until the establishment demonstrates its ability to meet the performance standard.

The probability of an establishment failing the Agency's pathogen reduction standard three consecutive times is less than 1% when the establishment prevalence is at the limit of the standard.

Implementation Timetable for Pathogen Reduction Performance Standards

Slaughter establishments and establishments producing raw, ground, and comminuted product subject to these pathogen reduction performance standards must meet the *Salmonella* standard at the time the establishment is required to implement HACCP. As explained in section II above, HACCP implementation will be phased in based on establishment size over a period of 18 to 42 months following the date of publication of this final rule. FSIS originally proposed a single two-year delayed effective date for its *Salmonella* performance standards. Many commenters argued that it was not reasonable to hold all establishments to the same effective date, and, furthermore, that it was more logical to hold establishments to compliance with the standard after, rather than before, HACCP was in place. This proposition also was strongly endorsed by many people who attended an information briefing and public meeting held by FSIS in Kansas City, Missouri, on May 22, 1995, expressly for small meat and poultry establishments and small businesses (60 FR 25869, May 15, 1995). They questioned, among other things, the need for and wisdom of a common implementation date for large and small establishments.

Harmonizing the effective dates with implementation of HACCP is more consistent with the nature of the pathogen reduction standards as measures of what establishments can and should achieve through HACCP-based process control. It will bring 74% of the nation's slaughter production of meat and poultry (by weight) under the performance standard 18 months following publication of this final rule. It will also facilitate the transition to HACCP, for both the FSIS workforce and affected establishments, by requiring all establishments to meet the performance standards as they implement HACCP.

Response to Comments

FSIS proposed to require that all meat and poultry slaughtering establishments and establishments producing raw ground product conduct daily microbial testing to determine compliance with interim targets for the reduction of *Salmonella.* FSIS proposed to require a single qualitative test per day, with daily results to be accumulated over time to provide information regarding the performance of an establishment's process and to collect data sufficient for process control verification. Daily testing was considered the minimal sampling necessary to detect process deviations within a realistic time frame.

The three issues most commonly raised by commenters concerning the proposed microbial testing requirements were the proposed selection of *Salmonella* as the indicator organism, the frequency of proposed testing, and the disproportionate costs to small establishments. Some commenters also argued that the regulatory approach was not justified and exceeded FSIS's legal authority.

The Indicator Organism

Many commenters opposed the use of *Salmonella* as the indicator organism, arguing that its low incidence in beef makes it a poor indicator of pathogen reduction in the species, the positive/negative test result is a weak measure of process control, and, compared to some nonpathogenic alternatives such as generic *E. coli, Salmonella* tests are more difficult, time-consuming, and costly. Others commented that testing for *Salmonella* alone is unacceptable, as there is no direct correlation between the presence of this organism and other pathogens such as *E. coli* O157:H7, *Listeria,* and *Campylobacter.*

Various alternative indicator organisms were suggested, including generic *E. coli* (biotype I), total plate counts, Enterobacteriaceae, Total Viable Counts (TVC), and Aerobic Plate Counts (APC). Commenters who recommended alternatives stated that tests for these organisms would be better indicators for process control and fecal contamination levels than tests for *Salmonella.* Still others requested that more studies be conducted to determine which type of indicator organism would be most useful for verifying process control.

Some commenters recommended retaining *Salmonella* as the target for pathogen reduction, but suggested adding a requirement for generic *E. coli* testing because it serves effectively as an indicator of fecal contamination in all species. A minority of commenters supported the proposed use of *Salmonella* as the indicator organism because of its significance as a cause of foodborne illness and because there are relatively simple tests available for detecting *Salmonella.* Some commenters recommended requiring testing for *Salmonella* and additional pathogens in selected species or products based on the degree of public health risk posed by the pathogen. A number of consumer groups requested a pathogen goal of zero for *E. coli* O157:H7.

These comments are generally addressed by the FSIS decisions to require slaughter establishments to test for generic *E. coli* as a means to verify process control for fecal contamination, and to have FSIS conduct testing for *Salmonella* for pathogen reduction.

FSIS considers systematic measures to prevent and remove fecal contamination and associated bacteria, coupled with microbial testing to verify effectiveness, to be the state of the art in slaughter establishment sanitation. Further, FSIS believes that testing for generic *E. coli* is the appropriate and necessary means by which meat and poultry slaughter

establishments must verify their process controls. FSIS reviewed written comments received on the original proposal and comments made at the scientific conferences and public meetings, as well as available scientific data, and has decided to require slaughter establishments to conduct testing for generic *E. coli* to verify process controls.

The Agency has concluded that each kind of testing serves an important function. Both play a major part in the Agency's pathogen reduction efforts, and working in unison will permit the Agency to use its inspection resources more effectively, and efficiently, thereby enhancing inspection.

E. coli testing for process control verification and *Salmonella* testing to enforce the pathogen reduction performance standard both are aimed at FSIS's objective to reduce the incidence of disease caused by foodborne pathogens. However, *E. coli* testing and *Salmonella* testing aim at the objective from different directions.

An ongoing screen for generic *E. coli* serves both the establishment and FSIS as a means of verifying that a slaughter facility's process is ''in control'' with regard to prevention of fecal contamination of the carcasses being produced. In other words, it becomes a marker for verifying a slaughter establishment's adherence to the zero tolerance for fecal contamination. Such testing provides a standard measure for verification of process control at the critical slaughter stage of production. Without such a standard measure, there is no objective basis upon which either the establishment or FSIS can determine the adequacy of process controls, from one establishment to another, in preventing fecal contamination. It will permit establishments to make ongoing adjustments or changes to their slaughter process when necessary to meet the performance criteria. The test results will also guide FSIS's ongoing inspection, permitting adjustments in intensity and focus as appropriate.

Generic *E. coli* testing to verify process control alone, however, does not adequately address legitimate public health concerns about pathogenic bacteria in and on raw product. *E. coli* (except for certain pathogenic subgroups) is not itself a cause of foodborne disease. It is a ''surrogate marker'' or ''indicator'' for fecal contamination, which in turn is a source of many pathogens that may contaminate products. Fecal contamination, however, does not always correlate with the presence of pathogens; high levels of *E. coli* may be present without pathogens, and pathogens may be present without high *E. coli* levels. Because testing for *E. coli* cannot serve as a surrogate for the presence of *Salmonella*, FSIS's specific public health objective of reducing nationwide *Salmonella* levels on raw meat and poultry products, including raw ground products, requires a standard and a testing regime that are directed at that pathogen.

The pathogen reduction performance standard for *Salmonella* must be met by all inspected establishments producing raw meat and poultry products. Agency testing for *Salmonella* is necessary for enforcement of that requirement. Slaughter establishments' *E. coli* testing, a means for verifying process control for fecal contamination, should promote improved process controls which should, in turn, result in reductions of *Salmonella* and other pathogens. But, *E. coli* testing cannot measure actual reductions and control of *Salmonella* nor be the basis for Agency enforcement of the pathogen reduction standards.

The test results from both kinds of testing are valuable to the Agency in the shift to a HACCP-based regulatory regime, but their value comes from the way they work together to verify the effectiveness of an overall system of preventive process control. The Agency continues to believe that pathogen reduction in inspected establishments requires that establishments build into their operations preventive measures and systems to reduce the potential for pathogens to be on products to begin with, and that such systems must be establishment-produced and establishment-specific. The Agency's HACCP and Sanitation SOP's regulations are intended to do that. However, these regulations are not self-enforcing. The Agency's inspection mandate does not permit it to simply assume that an establishment's systems are in fact producing uniformly safe and unadulterated products. Pathogen reduction will be achieved instead by the combination of HACCP plans validated as effective for pathogens of concern, *E. coli* testing by the establishment to provide on-going verification of process control for fecal contamination, and *Salmonella* testing by FSIS to enforce compliance with the pathogen reduction performance standards.

Frequency and Cost of Testing

Many commenters questioned the proposed frequency of daily testing for each species and for raw, ground products. The majority of commenters who opposed daily testing stated that this testing requirement would place an unfair cost burden and have a negative economic impact on some establishments, especially small volume establishments and establishments producing multiple species and multiple ground products that would require multiple tests. These commenters stated that under the proposed sampling methodology, a small establishment could conceivably conduct more tests per day than a very large establishment with a much higher production volume. Also mentioned was the fact that many of these establishments do not have on-site testing facilities and would have an additional cost of shipping samples for testing.

To minimize the economic impact on establishments, especially small establishments, some commenters suggested that FSIS should pay for microbial testing. Others recommended less than daily testing or other changes to the proposed sampling frequency. Various alternatives to the proposed sampling protocol were mentioned, but the sampling scheme recommended most often as the most equitable, and the one FSIS is requiring, is one based on production volume.

Although many commenters requested less frequent testing than that proposed, others supported the one sample per day testing requirement as an efficient means of verifying process control. Still others recommended testing even more frequently than once per day. These commenters asserted that testing once a day is inadequate to verify process control or to screen out product with pathogens. Their main concern was that the proposed sampling frequency and moving sum statistical procedure would allow inadequate process control to go undetected, resulting in large quantities of suspect product being produced; recommendations were made for a testing frequency more proportional to an establishment's production volume.

Some commenters requested that exemptions from the proposed daily microbial testing be made for small establishments and establishments that have consistently complied with their HACCP programs. Others requested exemptions for specific products including: raw ground meat products; cured products; thermally processed canned foods; frozen foods; boxed meat and beef and pork carcasses from other inspected establishments; minor species (i.e., sheep, lamb, goats, equines, guineas); and raw ground products to be further processed as fully cooked, ready-to-eat items, while others stated that exemptions for these items would be inappropriate.

FSIS has modified the proposal in response to these comments. As explained above, FSIS is requiring *E. coli* testing in slaughter establishments where the initial and primary opportunity for fecal contamination occurs. FSIS is not requiring *E. coli* testing of processed products. A more limited testing requirement is possible because oversight of slaughter establishment verification testing for *E. coli* is not the sole means relied upon by FSIS to detect or prevent lack of process control. It is only one of many aspects of establishment operations FSIS will inspect in assessing the adequacy of an establishment's process controls. In particular, FSIS will increasingly rely on its verification that HACCP systems are working as intended. HACCP principles require establishments to identify CCP's, monitor them to see that they are in control, and take appropriate corrective action when monitoring detects a deviation. This is where control must be exercised by the establishment and where any lack of control will be detected in a establishment operating under a validated HACCP system.

FSIS has reconsidered the proposed requirement of daily testing in all slaughter establishments, in part because of the unnecessary and disproportionate economic impact that would occur for some small establishments. Instead, FSIS is requiring slaughter establishments to test carcasses for generic *E. coli* at frequencies corresponding to production volume. In addition, slaughter establishments will have 6 months, not just 3 months as proposed, after publication of the final rule to begin testing carcasses for generic *E. coli*. Further, very low volume establishments may not need to do more than one set of 13 *E. coli* tests annually, and such establishments slaughtering more than one species need not test both. These changes will significantly reduce the cost impact of mandatory testing for small establishments, while providing adequate and useful information to verify process control.

In addition to requiring testing for generic *E. coli* by slaughter establishments at a frequency relative to the establishment's production volume, *Salmonella* testing will be conducted by FSIS.

''Minor species,'' such as sheep, goats, equines, ducks, geese, and guineas, are not being addressed at this time because the Agency is addressing first the most commonly consumed foods under its jurisdiction. FSIS intends to address how best to gather data on and develop testing requirements and performance criteria and standards for these other food animals at a future date.

Legal Authority for Testing Requirement

Several commenters have questioned FSIS's legal authority for the proposed microbiological testing program. These comments are still relevant despite the differences between the proposed and final rules for microbiological testing.

The major change in the final rule is that FSIS is not adopting the proposed *Salmonella* testing regimen. As proposed, results of a series of establishment-conducted *Salmonella* tests would have been used to accomplish two goals: to verify process control and to enforce the prevalence targets for pathogens in raw products. Instead, FSIS is promulgating separate provisions to address these two regulatory goals. The first provision requires that slaughter establishments test carcasses for *E. coli* so that the effectiveness of the establishment's sanitation and process control measures can be assessed in an objective, uniform manner. The second provision sets a pathogen reduction performance standard to bring about reductions in the prevalence of *Salmonella* on raw meat and poultry products. This standard will be enforced by an FSIS-conducted testing program, and will require establishments with prevalence of *Salmonella* above the standard to change their operations to meet that standard. Failure by an establishment to achieve the standard could result in Agency sanctions, as discussed above. This standard will also encourage innovation to reduce pathogens throughout the industry.

One commenter argues that, because this regulatory strategy is precedent-setting, FSIS has a greater than usual burden of articulating the legal basis for it. This commenter notes that the testing regulation does not rely on a finding that the presence of the targeted organisms causes specific lots of product to become adulterated, as is the case with *E. coli* O157:H7 in ground beef. This commenter then argues that FSIS is relying upon a vague ''sanitation theory'' as its legal basis, and that the Agency has a greater duty to articulate its legal basis when new regulations impose new kinds of costs, like mandatory *E. coli* testing, or when the Agency is establishing a new regulatory policy.

This commenter believes that FSIS reliance on a ''sanitation theory'' is legally flawed because, if the Agency is unable to tell establishments how to correct a failure to meet the established targets, it cannot legally require microorganism testing, or impose sanctions for failure to meet established standards.

FSIS has ample statutory authority under the FMIA and PPIA to promulgate these microbiological testing provisions. The meat and poultry inspection statutes mandate Federal regulatory oversight of unusual intensity and comprehensiveness, and they provide the Secretary broad rulemaking authorities to implement them. The primary goal of the statutes is to prevent adulterated or misbranded meat and poultry products from entering into commerce by inspecting meat and poultry products and the establishments that produce them before the products are introduced into commerce. Such inspections are supplemented by compliance actions to remove adulterated or misbranded products from commerce and to apply appropriate sanctions against violators of the law. FSIS regulations under the FMIA and PPIA may be divided into two categories: (1) regulations prescribing the conditions under which, and the manner in which, mandatory inspections are conducted; and (2) regulations directed more broadly at preventing adulteration or misbranding of products, preparation of products in violation of the law, and sale of such products in commerce.

These two regulatory categories are interrelated. The broader category is similar to regulations imposed on foods generally by the FDA under the Federal Food, Drug, and Cosmetic Act. However, FSIS authorities also require compliance with the inspection provisions of the acts and regulations by anyone slaughtering poultry or livestock, or preparing poultry products, or meat or meat food products for use as human food. Thus, the requirements that establishments must meet to obtain inspection and to have products marked ''inspected and passed'' comprise a unique statutory scheme which provides the Secretary with broad rulemaking authorities.

From their inception, the meat and poultry inspection laws have recognized that sanitary conditions in establishments are critical to the safety and wholesomeness of the products being produced. Any product found to have been ''prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health'' is adulterated. No product will be granted inspection or marked ''inspected and passed'' unless the sanitary conditions and practices required by the Secretary are maintained.

It is important to distinguish the statutorily required finding that a product is not adulterated from the absence of a finding that it is adulterated. Only products found not to be adulterated may be marked ''inspected and passed.'' Even if the evidence does not compel an inspector to find that a product is adulterated, it, nonetheless, may be enough to prevent him from finding that it is not adulterated. This means that products may not be distributed for food use without the affirmative determination that they are not adulterated. Products as to which such an affirmative determination has not been made must be retained at the establishment pending such determination. They are being detained because they have not been inspected and passed, not because they have been found to be adulterated.

Thus, FSIS clearly has the authority to require that establishments slaughtering livestock or poultry conduct and record tests for *E. coli* on carcasses to measure how well contamination is being avoided. These tests provide information by which establishments may evaluate and ensure the effectiveness of their sanitary procedures and related process controls in preventing product contamination during slaughter and dressing.

Although *E. coli* testing will not be used to determine the disposition of inspected products, it will be an effective indicator of the presence of fecal contamination that is not visible and therefore not detectable by traditional inspection methods. It will also provide FSIS with information necessary to determine how best to conduct inspection to ensure that product is not being adulterated.

Similarly, FSIS has clear authority to establish a *Salmonella* standard for producers of raw meat and poultry to reduce the public's exposure to *Salmonella* and associated pathogens from inspected meat and poultry products. The *Salmonella* standard, like the criteria for *E. coli* on carcasses, is based on the national baseline prevalence of the bacteria for the product of concern. However, unlike the *E. coli* criteria, which are, in essence, guidelines, the *Salmonella* standard must be met. Compliance will be determined by Agency testing.

FSIS is continuing its policy of permitting raw meat and poultry products to be marked and labeled ''inspected and passed,'' despite the known or suspected presence of some pathogenic bacteria. FSIS recognizes that currently there is no available technology (with the possible exception of irradiation) to ensure that raw product bears no pathogenic microorganisms.

However, there is overwhelming evidence that raw meat and poultry products are frequently contaminated with pathogens and expose consumers to avoidable and unacceptable risks of foodborne illness. FSIS's statutory mandate to protect consumers from adulterated product is not limited to actions associated with inspection. The Secretary may also regulate how meat and poultry products are stored and handled by anyone who buys, sells, freezes, stores, transports, or imports them, to ensure they are not misbranded or adulterated when delivered to the consumer.

The new pathogen reduction standards for *Salmonella* are necessary to establish that raw product is being produced under sanitary conditions, has not been prepared, packed or held under insanitary conditions, and is not for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.

The fact that the new performance standards and guidelines do not specify how the *E. coli* process control verification performance criteria or the *Salmonella* pathogen reduction standard must be met does not undercut the reasonableness or the legal basis of either testing program. Process control and the production of product that is not adulterated is the responsibility of the establishment, not the government. The Agency is responsible for establishing and enforcing reasonable standards; it intends to give the industry the maximum flexibility to decide how best to meet such standards. It does not intend to regulate or prescribe how the standards are to be met. FSIS will provide guidance and assistance to the industry, especially small businesses. But it is not legally obliged to provide technical services to establishments in finding the most efficient and effective way to operate within the *E. coli* criteria and to meet the *Salmonella* reduction standard.

In summary, FSIS has concluded that the *E. coli* testing program and the *Salmonella* reduction standard are fully supported by the FMIA and PPIA.

Performance Standards for Process Control

A related comment asserted that FSIS's proposed *Salmonella* standard was not a standard at all, but instead was merely an unenforceable criterion because its violation would not alone support seizure or condemnation of products. FSIS agrees with the principle that a regulatory standard should be enforceable, but does not agree that a regulatory ''standard'' must be limited to product-specific requirements, or to enforcement by seizure or condemnation of products. The Agency acknowledges that historically it has used the term ''standard'' normally to refer to regulations concerning particular products, e.g., standards of identity regulations, but notes that current government-wide regulatory reform efforts stress the use of ''performance standards'' to describe the desired focus of government regulations generally. FSIS intends now to issue regulations consistent with the notion behind ''performance standards,'' that to the extent possible regulations should tell regulated entities what they must achieve to comply with the law, while providing maximum flexibility regarding how to achieve the standard. Thus, FSIS agrees that one test of a ''standard'' might be that violation of that requirement alone supports some sort of regulatory sanction, but does not agree that ''standards'' should be limited to product-specific regulations or to enforcement actions directed at specific products. The FMIA and PPIA do not limit the Agency to product-specific regulations and enforcement activities, and for reasons fully discussed earlier in this preamble, the Agency has concluded that standards directed at processes are, at this time, the only practical way in which to effectively address the hazard presented by microbiological pathogens on raw meat and poultry products.

Basis for Target Levels

Some commenters questioned the validity of microbial target levels established by FSIS, while others supported FSIS national baseline studies as an effective way to evaluate industry performance. After careful review, the Agency considers it reasonable and appropriate to use the distribution of results observed for each animal species in the FSIS baseline surveys as the basis for both the *E. coli* criteria and the pathogen reduction performance standard for *Salmonella*. These are currently the best available data on the nationwide prevalence and level of microbial contamination of raw meat and poultry products. The data demonstrate that the *E. coli* process control verification criteria and the *Salmonella* pathogen reduction standard are being achieved by many establishments with today's technology and therefore are achievable by all establishments.

FSIS Nationwide Microbiological Baseline Data Collection Programs and its Nationwide Microbiological Surveys provide similar data, but the

''Programs'' generally involve more extensive sampling over a longer period, generally 12 months, than the ''Surveys'', which are generally limited to 6 months of data collection. They both have provided data for an ongoing microbial profile of carcasses and other raw meat and poultry products for selected microorganisms or groups of microorganisms of various degrees of public health concern of value as indicators of general hygiene or process control.

As explained above, FSIS plans to revise the performance criteria and standards as more current baseline data become available from future baseline surveys, through establishment *E. coli* testing, through FSIS *Salmonella* testing, or from other FSIS testing that may be appropriate for establishing criteria and standards.

Although the majority of commenters focused on the issues mentioned above, a number of others addressed various aspects of the proposed rule such as microbial testing methodology, the concept of end product testing, the role of FSIS personnel in test verification, enforcement actions for non-compliance, and laboratory qualifications.

Methodology for Meeting Targets

Some commenters raised objections to use of the ''moving sum'' statistical procedure for determining when microbial testing results are within the process control. Moving sum procedures are recognized in the field of statistical quality control. The American National Standard ''Guide for Quality Control Charts'' [11] identifies two principal uses of such charts: assisting judgment as to whether a state of control exists and attaining and maintaining control. In order to judge whether a state of control exists, operators must analyze ''collectively an accumulation of quality data.'' In the proposed regulation FSIS took this view of the purpose of the moving sum procedure: establishments would need to verify that a state of control exists with respect to the interim target set by the Agency. FSIS did not claim, however, that the procedure would be useful for the second purpose, attaining and maintaining control. That requires more timely and probably more intense monitoring of process parameters at CCP's.

The proposed approach to use testing to measure process control was designed to inform establishments how they are currently operating with respect to the relevant target, and to help them track progress toward meeting that target. A simple plot of the moving sum chart would give them sufficient feedback for this purpose.

Some commenters recommended that the moving window verification program should use a 90% probability criteria, rather than 80%, to reduce the possibility of the testing procedure erroneously identifying an establishment as not meeting the pathogen target. The Agency notes that the moving sum procedure was designed to measure effectiveness of process control with respect to an interim performance standard (called a target in the proposal) based on current industry performance (as determined by a baseline study). This measure was intended to be the first step in holding establishments accountable for meeting acceptable levels of performance. As such, the Agency wanted to be able to readily identify establishments operating above the target and wanted to provide an incentive for establishments to produce at levels better than (below) the target. Giving establishments producing at the target only an 80% chance of passing was expected to promote this. Giving establishments producing at the target a higher chance of passing (e.g., 95%) would reduce both the incentive to do better and the ability to detect establishments above the target.

Sample Size

Others specifically addressed the proposed sample size, recommending that the same number of samples be used for all species. Not all species have the same risks of failure, in part because of the varied incidence of pathogens, as was determined in FSIS's baseline surveys. The proposed sampling rate was the same for all establishments, one per day. Thus the sampling was the same for all establishments, only the rules for interpreting results were different. The number of results included in the window differed by product class because the target percents positive differed by product class. It was necessary to employ different-sized windows to maintain a fixed probability of passing (80%) at the target for all product classes while choosing as short a window as possible and allowing at least one positive in the window.

Testing Methodology

Other commenters asked for clarification on testing methodology. Some remarked that using a sponge or swab method to sample carcasses is preferable to the proposed excision method because the proposed method is time consuming, cumbersome, and expensive, and it may mutilate and contaminate the carcass. The Agency agrees and has elected to use non-destructive sampling methods.

Others asked for clarification of enforcement actions that would result from an establishment not meeting its microbial targets. How the rule will be enforced is addressed above.

Role of Inspectors

Still others asked about the role of inspection personnel in verification testing and expressed concern about the amount and type of training inspection personnel would receive to analyze test results.

The final rule makes slaughter process control verification testing (*E. coli*) the responsibility of establishments slaughtering livestock or poultry, although FSIS inspectors may also collect samples for *E. coli* testing as needed to carry out their oversight responsibilities. FSIS personnel sampling carcasses for *Salmonella* to ensure that establishments are meeting the pathogen reduction performance standard will send the samples to an Agency laboratory for analysis. FSIS personnel have been involved in collection of samples for FSIS's baseline surveys, and have been trained and are highly qualified to collect samples for this regulatory program. Inspectors will work with other program officials, including scientifically trained experts, in analyzing test results and making appropriate regulatory decisions. Inspectors will receive training to prepare them for their role in this process.

Laboratories

Some commenters asked for clarification regarding qualifications for in-house and outside laboratories. They stated that laboratories should be required to use standardized techniques for analyzing test results.

The microbiological test method used by the establishments must be AOAC validated techniques, or other methods validated by a scientific body in collaborated trials against the three tube most probable number (MPN) method and agreeing with the 95 percent upper and lower confidence interval, as discussed in the *E. coli* Methods Section. Establishments are responsible for the accuracy of the tests of their samples. If the samples are not analyzed by the establishment, the establishment, perhaps in concert with a trade association, should ensure that the laboratory it chooses is reputable and

[11] American National Standard ANSI Z1.1–1985. ''Guide for Quality Control Charts.'' American Society for Quality Control. Milwaukee, WI.

adheres to a Quality Control/Quality Assurance Program.

Alternative Sampling Under HACCP

Other commenters stated that the proposed microbial testing system does not reward very clean establishments by granting reasonable reductions in testing when significant periods are pathogen free. They recommended that once a facility has implemented its HACCP program, the required frequency for mandatory microbial testing should be reduced or eliminated altogether.

In this final rule, a slaughter establishment successfully operating under a validated HACCP plan may reduce the specified sampling frequency as long as the alternative sampling plan is an integral part of the establishment's verification procedures for its HACCP system. FSIS does, however, reserve the right to determine that the alternative frequency is inadequate to verify the effectiveness of the establishment's process controls. In that case, FSIS would notify the establishment in writing of its finding, advise that the frequency specified in the regulation must be maintained, and specify any conditions an acceptable alternative frequency would have to meet to be found acceptable to the Agency.

Relationship to HACCP

Finally, some commenters stated that the proposed end-product testing is inconsistent with HACCP principles and that establishments should decide for themselves through hazard analysis whether testing is needed and at what frequency. Others objected to the concept of end-product testing because it only measures effectiveness over a small percentage of a production lot and has limited value in measuring the overall success of a HACCP plan. Still others concluded that placing an emphasis on end-product testing gives consumers a false sense of confidence about the safety of meat and poultry products. A few commenters were concerned about product liability due to product recalls stemming from test results.

The objective of the generic *E. coli* testing is to verify that process control has been maintained by the establishment throughout the slaughter and dressing process and that resultant carcasses are produced hygienically. If processes are under control for *E. coli*, the potential presence of enteric pathogens will be reduced. End-product verification testing of this kind is a well recognized component of HACCP-based process control.[12] The goal of FSIS's *Salmonella* testing program is to verify that pathogen reduction performance meets current standards in each establishment and thereby effect a nationwide reduction in the incidence of that organism and other enteric pathogens on raw meat and poultry products. The end of production is the only point that reflects all steps in the production process and, ultimately, all elements of the HACCP system. The seventh HACCP principle is verification that the HACCP system is working; one cannot verify that HACCP is working in slaughter establishments (controlling fecal contamination/pathogens) without some end-product testing, so end-product testing is not inconsistent with HACCP principles. The two different kinds of testing programs: (1) *E. coli* testing by establishments to verify control of fecal contamination; and (2) *Salmonella* testing by FSIS to hold establishments accountable for meeting pathogen performance standards, are both forms of end-product testing that FSIS considers consistent with HACCP.

End-product testing as part of an overall system of HACCP-based process control and performance standards should not give consumers a false sense of confidence about the safety of meat and poultry products. FSIS recognizes that limited end-product testing alone provides little assurance of safety, but, as part of a process control system, appropriate end-product testing brings rigor and accountability to the system and should appropriately increase consumer confidence in the safety of products. By requiring HACCP, FSIS is in fact moving away from sole reliance on end-product assessments for lot acceptance, an approach that is the opposite of the HACCP system approach to food safety. FSIS recognizes that producing safe food requires preventing hazards throughout the process rather than relying solely on end-product testing to ensure safety. Establishments' liability to civil lawsuits should not be adversely affected by this rule precisely because it is an establishment's process, not individual lots of product, that is being assessed, for inspection purposes, on the basis of this testing.

V. Other Issues and Initiatives

Antimicrobial Treatments

FSIS proposed that all slaughter establishments apply at least one antimicrobial treatment or other approved intervention to livestock and poultry carcasses prior to the chilling or cooling operation. Proposed treatment methods included chlorine compounds, hot water, and any antimicrobial compound previously approved by FSIS and listed in the meat or poultry regulations. Product prepared for export to countries that restrict or prohibit the use of antimicrobial treatments would have been exempted from this requirement upon application to the Administrator.

While most commenters generally agreed that antimicrobial treatments could play an important role in reducing contamination with pathogenic microorganisms in slaughter establishments, many commenters opposed mandating such treatments. The commenters argued that mandating the use of antimicrobial treatments in slaughter operations would not be consistent with the HACCP philosophy and the overall shift by FSIS to greater reliance on performance standards.

FSIS agrees with these commenters and has decided not to mandate the use of antimicrobial treatments in slaughter establishments. FSIS continues to believe that slaughter establishments will find that these treatments can play a useful role in reducing pathogens and improving the safety of meat and poultry products. Rather than mandating specific antimicrobial treatments, FSIS will rely on other requirements in this final rule to ensure that slaughter establishments are achieving an acceptable level of performance in controlling and reducing harmful bacteria on raw product.

The principle of using antimicrobial treatments as an intervention to control pathogens on meat and poultry carcasses was strongly endorsed by most commenters. However, few agreed that the treatments should be mandatory. A majority of commenters recommended that antimicrobial treatments be voluntary interventions. Establishments would decide if antimicrobial interventions were needed to control specific hazards at one or more critical control points in the slaughter process.

Similarly, a number of commenters tied antimicrobial treatments to microbial testing. They argued that carcass treatments should not be required in establishments that consistently meet or exceed performance standards for microbial contamination.

Commenters said FSIS should focus its regulatory efforts on measurable, attainable goals and not on prescriptive requirements for particular processing steps. Several commenters emphasized the need for ''whole system'' interventions instead of single

[12] National Advisory Committee on Microbiological Criteria for Foods. 1994. ''Hazard Analysis and Critical Control Point Systems.'' FSIS, USDA.

techniques such as antimicrobial treatments. They said these interventions work best when they are tailored to species and product hazards, individual establishment configurations, and processing methods. Furthermore, some commenters cited a danger that establishments and inspection personnel would focus on the treatment function itself instead of broader food safety goals.

FSIS generally agrees with these comments. FSIS has concluded that its food safety goals can be achieved more effectively and more efficiently by requiring HACCP-based process control combined with appropriate performance criteria and standards than by mandating specific interventions, such as antimicrobial treatments. New technological interventions will play a significant role in reducing the risk of foodborne illness and should be adopted as part of an overall system of HACCP-based process control. FSIS expects that such treatments may be used by establishments to meet the process control performance criteria and pathogen reduction performance standards FSIS is adopting in this final rule.

A few commenters opposed mandating antimicrobial treatments because they believed their use would allow for correction of sloppy carcass dressing procedures. These commenters argued that antimicrobial treatments, whether mandatory or voluntary, emphasize post-contamination clean-up rather than prevention.

FSIS also received many comments which addressed the four proposed antimicrobial treatment methods. Many commenters stated that FSIS should not restrict establishments to these particular antimicrobial interventions.

A variety of commenters addressed technology issues concerning the proposed treatment methods themselves. Many said that too few studies have been conducted to show which interventions are most effective and efficient for specific pathogens associated with particular species in individual slaughter establishment configurations. Some argued that the studies FSIS cited in its proposal were too narrow and did not adequately demonstrate effectiveness. They said additional studies were needed to determine the practicality, efficacy, and expense of various antimicrobial treatments in commercial settings. In addition, some commenters were concerned that insufficient research was available on whether the elimination of competitive micro flora would allow uninhibited growth of pathogenic bacteria.

Individual antimicrobial techniques were also criticized. For example, hot water sprays were said to pose dangers to establishment personnel applying the treatments at temperatures necessary for effectiveness. Hot water sprays raise carcass temperatures with consequent melting of surface fat in some species, contribute to quality defects such as change in product color and partial cooking, and result in higher energy costs. Commenters recognized, however, that hot water was the only currently available nonchemical intervention that could be implemented at comparatively low cost. Other commenters criticized lactic, acetic, and citric acid solution sprays because they have low effectiveness as a treatment against *E. coli* O157:H7. The possible carcinogenic effects of chlorine were also mentioned, as were concerns about water reuse and possible environmental effects from spray effluents.

Commenters also suggested a variety of alternative antimicrobial interventions that could be used by establishments. These interventions included irradiation and radiation-emitting electronic devices such as x-rays and linear accelerators; high-energy ultraviolet light; pulsed light, sonic, infrasonic, and ultrasonic emitters; chemicals such as copper sulfate in the pentahydrate form, chlorine dioxide, and hydrogen peroxide; procedures such as pre-evisceration washes, water curtains, counter current or counter flow scalders, the *Peroxi bicarb* process, automatic warm fresh water rinses, ozonated water, steam pasteurization, steam vacuuming, hot wax dipping, and singeing.

A number of commenters also suggested that FSIS establish protocols to evaluate various forms of antimicrobial procedures and treatments. FSIS could then publish a regularly updated list of acceptable treatments and provide guidelines for their use in a commercial setting. It was argued that this process would give establishments the flexibility to implement any interventions they deem necessary. Others said FSIS should set up a predetermined protocol for antimicrobial agents or an expedited review process for new technologies.

FSIS agrees that issues of effectiveness, product and worker safety, product quality, interference with inspection, and environmental impact can be raised about most food safety interventions, including antimicrobial treatments. Therefore, to facilitate industry development of new technologies, FSIS has established a process that will facilitate this development.

On May 25, 1995, FSIS published a notice in the Federal Register (60 FR 27714) that presented guidelines for preparing and submitting experimental protocols to FSIS for use by establishments wishing to conduct trials of new technologies and procedures. In that notice, FSIS confirmed its long-standing commitment to foster innovative technologies and procedures that more effectively protect meat and poultry products from microbiological and other hazards. Specifically, FSIS encouraged the development of efficacious, practical and manageable technologies and procedures by establishments.

FSIS also published guidelines (FSIS Directive 10,700.1) for establishments to use for submitting written proposals and protocols to FSIS for approval to conduct experiments. Agency approval is required in cases where the intended technology, procedure or process may affect (1) product safety or lead to economic adulteration, (2) worker safety, (3) environmental safety, or (4) inspection procedures.

Similarly, FSIS published a proposed rule in the Federal Register (60 FR 67459; December 29, 1995) that will facilitate the review and approval of substances intended for use in or on meat and poultry products. Under the proposed procedures, FSIS would no longer issue its own regulations listing substances it finds suitable for use in meat and poultry products. Instead, FDA's regulations would specify whether a substance approved for use in foods under the Federal Food, Drug, and Cosmetic Act may be used in or on meat or poultry products.

Many commenters stated that antimicrobial interventions should be permitted at any stage in the slaughter process: live animal, pre-hide removal, pre- or post-carcass wash, pre- or post-chill, or just prior to fabrication.

Some commenters argued that the proposed treatments would seriously compromise the Kosher ritual salting process, while others said the interventions would conflict with Confucian and Buddhist-style poultry prepared for religious rites.

A number of commenters questioned the relationship between FSIS's policy on zero tolerance for fecal contamination and its antimicrobial treatment proposal. In particular, they were concerned about where in the process zero tolerance would be measured.

Finally, several commenters requested a practical definition of ''feces'' as a means to resolve disagreements between inspectors and establishment personnel about trimming contamination.